

Record #1 of 370



ID: CN-00983832

AU: Reches A

AU: Laufer I

AU: Ziv K

AU: Cukierman G

AU: McEvoy K

AU: Ettinger M

AU: Knight RT

AU: Gazzaley A

AU: Geva AB

TI: Network dynamics predict improvement in working memory performance following donepezil administration in healthy young adults.

SO: NeuroImage

YR: 2014

VL: 88

PG: 228-241

XR: EMBASE 2014082224

PT: Journal: Article

KY: adult; algorithm; article; Brain Network Activation; *cognition; controlled study; double blind procedure; electroencephalogram; event related potential; female; frontal posterior theta alpha sub network; human; human experiment; male; *nerve cell network; normal human; priority journal; single drug dose; task performance; visual memory; *working memory; *donepezil/ct [Clinical Trial]; *donepezil/po [Oral Drug Administration]; placebo

DOI: <http://dx.doi.org/10.1016/j.neuroimage.2013.11.020>

AB: Attentional selection in the context of goal-directed behavior involves top-down modulation to enhance the contrast between relevant and irrelevant stimuli via enhancement and suppression of sensory cortical activity. Acetylcholine (ACh) is believed to be involved mechanistically in such attention processes. The objective of the current study was to examine the effects of donepezil, a cholinesterase inhibitor that increases synaptic levels of ACh, on the relationship between performance and network dynamics during a visual working memory (WM) task involving relevant and irrelevant stimuli. Electroencephalogram (EEG) activity was

recorded in 14 healthy young adults while they performed a selective face/scene working memory task. Each participant received either placebo or donepezil (5. mg, orally) on two different visits in a double-blinded study. To investigate the effects of donepezil on brain network dynamics we utilized a novel EEG-based Brain Network Activation (BNA) analysis method that isolates location-time-frequency interrelations among event-related potential (ERP) peaks and extracts condition-specific networks. The activation level of the network modulated by donepezil, reflected in terms of the degree of its dynamical organization, was positively correlated with WM performance. Further analyses revealed that the frontal-posterior theta-alpha sub-network comprised the critical regions whose activation level correlated with beneficial effects on cognitive performance. These results indicate that condition-specific EEG network analysis could potentially serve to predict beneficial effects of therapeutic treatment in working memory. 2013 Elsevier Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/832/CN-00983832/frame.html>

Record #2 of 370



ID: CN-00984299

AU: Andrykowski MA

AU: Steffens RF

AU: Bush HM

AU: Tucker TC

TI: Disparities in mental health outcomes among lung cancer survivors associated with ruralness of residence.

SO: Psycho-oncology

YR: 2014

VL: 23

NO: 4

PG: 428-36

XR: EMBASE 2014237335

PT: Journal: Article

KY: adult; anxiety; article; cancer registry; *cancer survivor; comorbidity; comparative study; controlled clinical trial; controlled study; depression; distress syndrome; education; effect size;

female; *health disparity; human; *lung non small cell cancer; major clinical study; male;
*mental health; outcome assessment; population based case control study; *residential care;
*rural area; telephone interview

DOI: <http://dx.doi.org/10.1002/pon.3440>

AB: Objective Healthy People 2020 identifies elimination of health disparities as a key aim. Rural residence is associated with disparities in cancer screening, physical morbidity, and survival. The present study aimed to identify potential disparities in mental health (MH) outcomes (e.g., anxiety and depression symptoms, distress) in lung cancer (LC) survivors associated with ruralness of residence. Methods Lung cancer survivors (LC group; n = 193; mean age = 63.1 years; mean time since diagnosis = 15.6 months) were recruited from the population-based SEER Kentucky Cancer Registry. LC survivors completed a telephone interview and questionnaire assessing MH outcomes. U.S. Department of Agriculture Rural-Urban Continuum Codes were used to identify Rural (n = 117) and Urban (n = 76) LC survivors. A healthy comparison (HC) group was recruited (n = 152) and completed a questionnaire assessing MH outcomes. Results Across six MH indices, Rural LC survivors reported poorer MH relative to Urban LC survivors with a mean effect size (ES) of 0.43 SD in unadjusted analyses and 0.29 SD in analyses adjusted for education and physical comorbidity. Comparison of the LC and HC groups revealed significant Ruralness x Group interactions for five of six MH indices. The Rural LC group reported poorer MH than the Rural HC group with a mean ES of 0.51 SD. The MH of Urban LC and HC groups did not differ (mean ES = 0.00 SD). Conclusions Rural residence is a risk factor for poorer MH outcomes for LC survivors. The MH of Rural LC survivors may be more negatively impacted by cancer diagnosis and treatment than the MH of Urban LC survivors. Copyright 2013 John Wiley & Sons, Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/299/CN-00984299/frame.html>

Record #3 of 370



ID: CN-00985164

AU: Al-Shaar L

AU: Mneimneh R

AU: Nabulsi M

AU: Maalouf J

AU: Fuleihan GE-H

TI: Vitamin D3 dose requirement to raise 25-hydroxyvitamin D to desirable levels in adolescents: Results from a randomized controlled trial.

SO: Journal of bone and mineral research

YR: 2014

VL: 29

NO: 4

PG: 944-51

XR: EMBASE 2014204928

PT: Journal: Article

KY: adolescent; alkaline phosphatase blood level; article; body mass; calcium blood level; calcium intake; controlled study; dose response; double blind procedure; drug megadose; female; human; low drug dose; male; normal human; phosphate blood level; physical activity; post hoc analysis; randomized controlled trial; sun exposure; treatment response; *vitamin blood level; vitamin supplementation; *25 hydroxyvitamin D/ec [Endogenous Compound]; alkaline phosphatase/ec [Endogenous Compound]; calcium/ec [Endogenous Compound]; *colecalciferol/ct [Clinical Trial]; *colecalciferol/do [Drug Dose]; osteocalcin/ec [Endogenous Compound]; phosphorus/ec [Endogenous Compound]; placebo

DOI: <http://dx.doi.org/10.1002/jbmr.2111>

AB: Several organizations issued recommendations on desirable serum 25-hydroxy vitamin D [25(OH)D] levels and doses of vitamin D needed to achieve them. Trials allowing the formulation of evidence-based recommendations in adolescents are scarce. We investigated the ability of two doses of vitamin D₃ in achieving recommended vitamin D levels in this age group. Post hoc analyses on data from a 1-year double-blind trial that randomized 336 Lebanese adolescents, aged 13 + 2 years, to placebo, vitamin D₃ at 200 IU/day (low dose), or 2000 IU/day (high dose). Serum 25(OH)D level and proportions of children achieving levels >20 ng/mL and 30 ng/mL were determined. At baseline, mean 25(OH)D was 15 + 7 ng/mL, 16.4 + 7 ng/mL in boys, and 14 + 8 ng/mL in girls, p = 0.003, with a level >20 ng/mL in 18% and >30 ng/mL in 5% of subjects. At 1 year, mean levels were 18.6 + 6.6 ng/mL in the low-dose group, 17.1 + 6 ng/mL in girls, and 20.2 + 7 ng/mL in boys, p = 0.01, and 36.3 + 22.3 ng/mL in the high-dose group, with no sex differences. 25(OH)D increased to >20 ng/mL in 34% of children in the low-dose and 96% in the high-dose group, being higher in boys in the low-dose arm only; it remained >30 ng/mL in 4% of children in the low-dose arm but increased to 64% in the high-dose arm. Baseline 25(OH)D level, body mass index (BMI), and vitamin D dose assigned were the most significant predictors for reaching a 25(OH)D level >20 ng/mL and 30 ng/mL. A daily dose of 2000 IU raised 25(OH)D level >20 ng/mL in 96% of adolescents (98% boys versus 93% girls). Dose-response studies are needed to determine in a definitive manner the daily allowance of vitamin D for Middle Eastern adolescents with a similar profile. 2014 American Society for Bone and Mineral Research.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/164/CN-00985164/frame.html>

Record #4 of 370



ID: CN-00984794

AU: Chapman J

TI: Vitamin E and Alzheimer's disease.

SO: Australian Journal of Pharmacy

YR: 2014

VL: 95

NO: 1126

PG: 92-3

XR: EMBASE 2014215996

PT: Journal: Short Survey

KY: *Alzheimer disease/dt [Drug Therapy]; alzheimers disease cooperative study score; caregiver activity scale; caregiver burden; controlled study; daily life activity; disease course; disease severity; drug effect; drug safety; follow up; functional assessment; human; infection/si [Side Effect]; infestation/si [Side Effect]; major clinical study; mental function; Mini Mental State Examination; outcome assessment; randomized controlled trial; rating scale; scoring system; short survey; *alpha tocopherol/ae [Adverse Drug Reaction]; *alpha tocopherol/ct [Clinical Trial]; *alpha tocopherol/cb [Drug Combination]; *alpha tocopherol/dv [Drug Development]; *alpha tocopherol/dt [Drug Therapy]; donepezil/dt [Drug Therapy]; galantamine/dt [Drug Therapy]; memantine/ae [Adverse Drug Reaction]; memantine/cb [Drug Combination]; memantine/dt [Drug Therapy]; placebo

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/794/CN-00984794/frame.html>

Record #5 of 370



ID: CN-00978588

AU: Sabbagh M

AU: Cummings J

AU: Christensen D

AU: Doody R

AU: Farlow M

AU: Liu L

AU: Mackell J

AU: Fain R

TI: Evaluating the cognitive effects of donepezil 23 mg/d in moderate and severe Alzheimer's disease: analysis of effects of baseline features on treatment response.

SO: BMC geriatrics

YR: 2014

VL: 13

PG: 56

PM: PUBMED 23742728

XR: EMBASE 23742728

PT: Journal: Article

KY: aged; *Alzheimer disease/dt [Drug Therapy]; *Alzheimer disease/ep [Epidemiology]; article; *cognitive defect/dt [Drug Therapy]; *cognitive defect/ep [Epidemiology]; controlled clinical trial; controlled study; double blind procedure; female; human; male; middle aged; multicenter study; psychological aspect; randomized controlled trial; *severity of illness index; treatment outcome; very elderly; *cholinesterase inhibitor/ad [Drug Administration]; donepezil; *indan derivative/ad [Drug Administration]; *piperidine derivative/ad [Drug Administration]

CC: SR-DEMENTIA

AB: Treatment of Alzheimer's disease with acetylcholinesterase inhibitors can result in symptomatic benefits, but patients often show variable responses. The objective of this post hoc analysis was to investigate relationships between easily identifiable baseline characteristics/demographics and cognitive response in patients treated with either donepezil 23 mg/d or 10 mg/d and to identify factors potentially influencing response. A post hoc analysis was conducted using data from a large, 24-week, randomized, double-blind, international study enrolling patients with moderate to severe Alzheimer's disease (baseline Mini-Mental State Examination [MMSE], 0-20) (NCT 00478205). Cognitive changes in subgroups of patients based on selected baseline and demographic characteristics were compared using the least squares mean changes in Severe Impairment Battery scores at Week 24. Univariate and multivariate analyses were also performed. Donepezil 23 mg/d provided statistically significant incremental cognitive benefits over donepezil 10 mg/d irrespective of

baseline functional severity, measured by scores on the Alzheimer's Disease Cooperative Study-Activities of Daily Living-severe version ($P < 0.05$). When patients were categorized by baseline cognitive severity (MMSE score), significant benefits of donepezil 23 mg/d over 10 mg/d were seen in both subgroups when based on MMSE scores of 0-9 versus 10-20 ($P < 0.02$ and $P < 0.01$, respectively), and in the more severe subgroup when based on MMSE scores of 0-16 versus 17-20 ($P < 0.0001$ and $P > 0.05$). Statistically significant incremental cognitive benefits of donepezil 23 mg/d over 10 mg/d were also observed regardless of age, gender, weight, or prestudy donepezil 10 mg/d treatment duration ($P < 0.05$). In the multivariate analysis, the only significant interaction was between treatment and baseline MMSE score. The cognitive benefits of donepezil 23 mg/d over 10 mg/d were achieved regardless of the patient's age, gender, weight, duration of prior donepezil 10 mg/d, and functional severity. The influence of baseline cognitive severity on response seemed to be dependent on the level of impairment, with cognitive benefits of donepezil 23 mg/d over 10 mg/d most apparent in those patients at a more advanced stage of disease. These data may be useful in helping practicing physicians make informed decisions for their patients with advanced Alzheimer's disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/588/CN-00978588/frame.html>

Record #6 of 370



ID: CN-00982797

AU: Darreh-Shori T

AU: Hosseini SM

AU: Nordberg A

TI: Pharmacodynamics of cholinesterase inhibitors suggests add-on therapy with a low-dose carbamylating inhibitor in patients on long-term treatment with rapidly reversible inhibitors.

SO: Journal of Alzheimer's disease

YR: 2014

VL: 39

NO: 2

PG: 423-40

XR: EMBASE 2014115036

PT: Journal: Article

KY: *add on therapy; aged; *Alzheimer disease/dt [Drug Therapy]; article; cerebrospinal fluid analysis; clinical article; combination chemotherapy; controlled study; double blind procedure; drug potentiation; enzyme inhibition; human; human tissue; long term care; priority journal; protein aggregation; protein expression; randomized controlled trial; *acetylcholinesterase/ec [Endogenous Compound]; amyloid beta protein/ec [Endogenous Compound]; *donepezil/ct [Clinical Trial]; *donepezil/cb [Drug Combination]; *donepezil/cm [Drug Comparison]; *donepezil/it [Drug Interaction]; *donepezil/dt [Drug Therapy]; *donepezil/pd [Pharmacology]; *phenserine/ct [Clinical Trial]; *phenserine/cb [Drug Combination]; *phenserine/cm [Drug Comparison]; *phenserine/it [Drug Interaction]; *phenserine/dt [Drug Therapy]; *phenserine/pd [Pharmacology]; placebo

DOI: <http://dx.doi.org/10.3233/JAD-130845>

AB: Despite three decades of intensive research in the field of Alzheimer's disease (AD) and numerous clinical trials of new therapeutic agents, cholinesterase inhibitors (ChEIs) are still the mainstay of therapeutics for AD and dementia with Lewy bodies. Pharmacodynamic analyses of ChEIs provide paradoxical observations. Treatment with the rapidly reversible, noncarbamylating ChEIs (donepezil, galantamine, and tacrine) increases acetylcholinesterase (AChE) protein expression, whereas the carbamylating agent, rivastigmine, produces sustained inhibition with no significant change in AChE protein expression. Still, the symptomatic clinical efficacies of all these agents are similar. We report here for the first time that treatment with phenserine, another carbamylating ChEI, produces a sustained but mild inhibition of AChE in cerebrospinal fluid (CSF) of AD patients. We also show that phenserine treatment reverses donepezil-induced elevation of AChE expression. Further analyses on CSF of another larger patient cohort treated with donepezil revealed that, in addition to its main mode of action, donepezil produced two other pharmacodynamics with potentially contradictory outcomes. Donepezil-induced AChE expression favored an AChE-driven amyloid-beta peptide (Abeta) aggregation, whereas donepezil itself concentration-dependently counteracted the AChE-induced Abeta aggregation, most likely by competing with the Abeta peptides for peripheral anionic site on the AChE protein. The reduction of AChE protein expression in the donepezil-treated patients by concomitant administration of the carbamylating agent, phenserine, could allow the donepezil molecule to only prevent interaction between Abeta and AChE. The current study suggests that an add-on therapy with a low-dose formulation of a carbamylating agent in patients on long-term donepezil treatment should be explored as a strategy for enhancing the clinical efficacy of these agents in dementia disorders. 2014 - IOS Press and the authors. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/797/CN-00982797/frame.html>

Record #7 of 370



ID: CN-00980322

AU: Pelton GH

AU: Andrews H

AU: Roose SP

AU: Marcus SM

AU: D'Antonio K

AU: Husn H

AU: Petrella JR

AU: Zannas AS

AU: Doraiswamy PM

AU: Devanand DP

TI: Donepezil treatment of older adults with cognitive impairment and depression (DOTCODE study): Clinical rationale and design.

SO: Contemporary Clinical Trials

YR: 2014

VL: 37

NO: 2

PG: 200-208

XR: EMBASE 2014051192

PT: Journal: Article

KY: adult; aged; Alzheimer Disease Assessment Scale; article; Clinical Global Impression scale; *cognitive defect/dt [Drug Therapy]; controlled study; dementia; *depression/dt [Drug Therapy]; female; Hamilton scale; human; long term care; major clinical study; male; middle aged; neuropsychological test; nuclear magnetic resonance imaging; outpatient; pilot study; scoring system; treatment outcome; very elderly; antidepressant agent; apolipoprotein E4/ec [Endogenous Compound]; *donepezil/dt [Drug Therapy]; placebo

CC: SR-DEMENTIA

DOI: <http://dx.doi.org/10.1016/j.cct.2013.11.015>

AB: Treatment strategies for patients with depression and cognitive impairment (DEP-CI), who are at high risk to develop a clinical diagnosis of dementia, are not established. This issue is addressed in the donepezil treatment of cognitive impairment and depression (DOTCODE) pilot clinical trial. The DOTCODE study is the first long-term treatment trial that assesses

differences in conversion to dementia and cognitive change in DEP-CI patients using a study design of open antidepressant medication plus add-on randomized, double-blind, placebo-controlled treatment with the acetylcholinesterase inhibitor donepezil. In Phase 1, DEP-CI patients receive optimized antidepressant treatment for 16. weeks. In Phase 2, antidepressant treatment is continued with the addition of randomized, double-blind treatment with donepezil or placebo. The total study duration for each patient is 78. weeks (18. months). Eighty DEP-CI outpatients (age 55 to 95. years) are recruited: 40 at New York State Psychiatric Institute/Columbia University and 40 at Duke University Medical Center. The primary outcome is conversion to a clinical diagnosis of dementia. The secondary outcomes are cognitive change scores in Selective Reminding Test (SRT) total recall and the modified Alzheimer's Disease Assessment Scale (ADAS-cog). Other key assessments include the 24-item Hamilton Depression Rating Scale and antidepressant response; Clinical Global Impression (CGI) for depression, cognition, and global status; neuropsychological test battery for diagnosis; informant report of functional abilities (Pfeffer FAQ); and Treatment Emergent Symptom Scale (TESS) for somatic side effects. Apolipoprotein E 4 status, odor identification deficits, and MRI entorhinal/hippocampal cortex atrophy at baseline are evaluated as neurobiological moderators of donepezil treatment effects. 2013 Elsevier Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/322/CN-00980322/frame.html>

Record #8 of 370



ID: CN-00981851

AU: Hort J

AU: Andel R

AU: Mokrisova I

AU: Gazova I

AU: Amlerova J

AU: Valis M

AU: Coulson EJ

AU: Harrison J

AU: Windisch M

AU: Laczó J

TI: Effect of donepezil in alzheimer disease can be measured by a computerized human analog of the morris water maze.

SO: Neurodegenerative Diseases

YR: 2014

VL: 13

NO: 2-3

PG: 192-6

XR: EMBASE 2014149236

PT: Journal: Article

KY: aged; *Alzheimer disease/dt [Drug Therapy]; article; cholinergic transmission; clinical article; computer; controlled clinical trial; controlled study; drug dose increase; drug effect; female; human; *human variant of Morris water maze test; male; Mini Mental State Examination; *Morris water maze test; outcome assessment; priority journal; recall; spatial orientation; task performance; *donepezil/ct [Clinical Trial]; *donepezil/dt [Drug Therapy]

DOI: <http://dx.doi.org/10.1159/000355517>

AB: Background: Drug development for Alzheimer disease (AD) is challenged by the success in animal models tested in the Morris water maze (MWM) and the subsequent failures to meet primary outcome measures in phase II or III clinical trials in patients. The human variant of MWM (hMWM) enables us to examine allocentric and egocentric navigation as in the MWM. Objective: It was the aim of this study to examine the utility of a computerized hMWM to assess the effects of donepezil in mild AD. Methods: Donepezil 5 mg/day was started after initial hMWM testing in the treated group (n = 12), and after 28 days, the dose was increased to 10 mg/day. The performance after 3 months was compared to that of a non-treated group (n = 12). Results: Donepezil stabilized or improved the spatial navigation performance after 3 months, especially in the allocentric delayed recall subtask (p = 0.014). Conclusions: The computerized hMWM has the potential to measure the effects of donepezil in mild AD. It is a sensitive cognitive outcome measure in AD clinical trials. 2013 S. Karger AG, Basel.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/851/CN-00981851/frame.html>

Record #9 of 370



ID: CN-00979671

AU: Pelton GH

AU: Andrews H

AU: Roose SP

AU: Marcus SM

AU: D'Antonio K

AU: Husn H

AU: Petrella JR

AU: Zannas AS

AU: Doraiswamy PM

AU: Devanand DP

TI: Donepezil treatment of older adults with cognitive impairment and depression (DOTCODE study): Clinical rationale and design.

SO: Contemporary Clinical Trials

YR: 2014

VL: 37

NO: 2

PG: 200-208

XR: EMBASE 2014051192

KY: adult; aged; Alzheimer Disease Assessment Scale; article; Clinical Global Impression scale; *cognitive defect/dt [Drug Therapy]; controlled study; dementia; *depression/dt [Drug Therapy]; female; Hamilton scale; human; long term care; major clinical study; male; middle aged; neuropsychological test; nuclear magnetic resonance imaging; outpatient; pilot study; scoring system; treatment outcome; very elderly; antidepressant agent; apolipoprotein E4/ec [Endogenous Compound]; *donepezil/dt [Drug Therapy]; placebo

DOI: <http://dx.doi.org/10.1016/j.cct.2013.11.015>

AB: Treatment strategies for patients with depression and cognitive impairment (DEP-CI), who are at high risk to develop a clinical diagnosis of dementia, are not established. This issue is addressed in the donepezil treatment of cognitive impairment and depression (DOTCODE) pilot clinical trial. The DOTCODE study is the first long-term treatment trial that assesses differences in conversion to dementia and cognitive change in DEP-CI patients using a study design of open antidepressant medication plus add-on randomized, double-blind, placebo-controlled treatment with the acetylcholinesterase inhibitor donepezil. In Phase 1, DEP-CI patients receive optimized antidepressant treatment for 16. weeks. In Phase 2, antidepressant treatment is continued with the addition of randomized, double-blind treatment with donepezil or placebo. The total study duration for each patient is 78. weeks (18. months). Eighty DEP-CI outpatients (age 55 to 95. years) are recruited: 40 at New York State Psychiatric Institute/Columbia University and 40 at Duke University Medical Center. The primary outcome is conversion to a clinical diagnosis of dementia. The secondary outcomes are cognitive change

scores in Selective Reminding Test (SRT) total recall and the modified Alzheimer's Disease Assessment Scale (ADAS-cog). Other key assessments include the 24-item Hamilton Depression Rating Scale and antidepressant response; Clinical Global Impression (CGI) for depression, cognition, and global status; neuropsychological test battery for diagnosis; informant report of functional abilities (Pfeffer FAQ); and Treatment Emergent Symptom Scale (TESS) for somatic side effects. Apolipoprotein E 4 status, odor identification deficits, and MRI entorhinal/hippocampal cortex atrophy at baseline are evaluated as neurobiological moderators of donepezil treatment effects. 2013 Elsevier Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/671/CN-00979671/frame.html>

Record #10 of 370



ID: CN-00979834

AU: Diniz BS

AU: Reynolds CF

AU: Begley A

AU: Dew MA

AU: Anderson SJ

AU: Lotrich F

AU: Erickson KI

AU: Lopez O

AU: Aizenstein H

AU: Sibille EL

AU: Butters MA

TI: Brain-derived neurotrophic factor levels in late-life depression and comorbid mild cognitive impairment: A longitudinal study.

SO: Journal of Psychiatric Research

YR: 2014

VL: 49

NO: 1

PG: 96-101


XR: EMBASE 2013820757

KY: aged; article; cognition; controlled study; disease association; female; follow up; human; *late life depression; longitudinal study; major clinical study; male; *mild cognitive impairment; neurologic examination; priority journal; protein blood level; *brain derived neurotrophic factor/ec [Endogenous Compound]; donepezil; placebo

DOI: <http://dx.doi.org/10.1016/j.jpsychires.2013.11.004>

AB: Changes in brain-derived neurotrophic factor (BDNF) level are implicated in the pathophysiology of cognitive decline in depression and neurodegenerative disorders in older adults. We aimed to evaluate the longitudinal association over two years between BDNF and persistent cognitive decline in individuals with remitted late-life depression and Mild Cognitive Impairment (LLD+MCI) compared to either individuals with remitted LLD and no cognitive decline (LLD+NCD) or never-depressed, cognitively normal, elderly control participants. We additionally evaluated the effect of double-blind, placebo-controlled donepezil treatment on BDNF levels in all of the remitted LLD participants (across the levels of cognitive function). We included 160 elderly participants in this study (72 LLD+NCD, 55 LLD+MCI and 33 never-depressed cognitively normal elderly participants). At the same visits, cognitive assessments were conducted and blood sampling to determine serum BDNF levels were collected at baseline assessment and after one and two years of follow-up. We utilized repeated measure, mixed effect models to assess: (1) the effects of diagnosis (LLD+MCI, LLD+NCD, and controls), time, and their interaction on BDNF levels; and (2) the effects of donepezil treatment (donepezil vs. placebo), time, baseline diagnosis (LLD+MCI vs. LLD+NCD), and interactions between these contrasts on BDNF levels. We found a significant effect of time on BDNF level ($p=0.02$) and a significant decline in BDNF levels over 2 years of follow-up in participants with LLD+MCI ($p=0.004$) and controls ($p=0.04$). We found no effect of donepezil treatment on BDNF level. The present results suggest that aging is an important factor related to decline in BDNF level. Clinicaltrials.gov Identifier: NCT00177671. 2013 Elsevier Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/834/CN-00979834/frame.html>

Record #11 of 370 

ID: CN-00982479

AU: Cumbo E

AU: Ligorì LD

TI: Differential effects of current specific treatments on behavioral and psychological symptoms in patients with alzheimer's disease: A 12-month, randomized, open-label trial.

SO: Journal of Alzheimer's disease

YR: 2014

VL: 39

NO: 3

PG: 477-85

XR: EMBASE 2014120209

PT: Journal: Article

KY: aged; aggression; agitation; *Alzheimer disease/dt [Drug Therapy]; anorexia/si [Side Effect]; anxiety; article; *behavior disorder; behavioral pathology in alzheimer disease scale; confusion/si [Side Effect]; controlled study; daily life activity; disease severity; drug effect; drug efficacy; drug safety; female; headache/si [Side Effect]; human; insomnia/si [Side Effect]; longitudinal study; major clinical study; male; *mental disease; Mini Mental State Examination; nausea/si [Side Effect]; neuropsychiatric inventory; open study; outcome assessment; parallel design; phobia; priority journal; prospective study; psychological rating scale; randomized controlled trial; restlessness/si [Side Effect]; sedation; treatment duration; treatment response; unspecified side effect/si [Side Effect]; very elderly; vomiting/si [Side Effect]; *donepezil/ae [Adverse Drug Reaction]; *donepezil/ct [Clinical Trial]; *donepezil/cm [Drug Comparison]; *donepezil/dt [Drug Therapy]; *galantamine/ae [Adverse Drug Reaction]; *galantamine/ct [Clinical Trial]; *galantamine/cm [Drug Comparison]; *galantamine/dt [Drug Therapy]; *memantine/ae [Adverse Drug Reaction]; *memantine/ct [Clinical Trial]; *memantine/cm [Drug Comparison]; *memantine/dt [Drug Therapy]; *rivastigmine/ae [Adverse Drug Reaction]; *rivastigmine/ct [Clinical Trial]; *rivastigmine/cm [Drug Comparison]; *rivastigmine/dt [Drug Therapy]

DOI: <http://dx.doi.org/10.3233/JAD-131190>

AB: Background: Behavioral and psychological symptoms of dementia (BPSD) occur in up to 80% of Alzheimer's disease (AD) patients and represent one of the most common reasons for early institutionalization and increase in management costs. Objectives: This study evaluated the effects of four drugs (memantine, donepezil, rivastigmine, galantamine) in BPSD in AD patients. Methods: This was a prospective, longitudinal, randomized, open-label, 4-arm, parallel-group, 12-month clinical trial carried out in 177 AD patients. The severity of BPSD was evaluated at baseline and after treatment with memantine (n = 48), donepezil (n = 42), rivastigmine (n = 46), and galantamine (n = 41), by using the Neuropsychiatric Inventory (NPI) and the Behavioural Pathology in Alzheimer's Disease (BEHAVE-AD) scales. Results: The NPI and BEHAVE-AD total scores improved from baseline to month 12 in all groups. The improvements in both scales were statistically significant in the memantine, donepezil, and rivastigmine groups, but not in the galantamine group. Responder analyses showed that treatment with memantine and rivastigmine resulted in more patients improving on NPI and BEHAVE-AD score, respectively. Agitation/aggression was the NPI item with the highest improvements (significantly versus baseline in the memantine and in the rivastigmine groups),

while aggression and anxiety/phobias were the mostly improved BEHAVE-AD items (significantly in the rivastigmine group for both and in the rivastigmine group only for anxiety/phobias). All treatments were well tolerated: most of adverse events reported were transient and of mild-to-moderate intensity. Conclusions: This study suggests that specific drugs for AD, especially memantine and rivastigmine, may be effective in the improvement of BPSD in patients with mild to moderate AD, without major side effects. 2014-IOS Press and the authors. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/479/CN-00982479/frame.html>

Record #12 of 370



ID: CN-00977887

AU: Vaidya JS

AU: Wenz F

AU: Bulsara M

AU: Tobias JS

AU: Joseph DJ

AU: Keshtgar M

AU: Flyger HL

AU: Massarut S

AU: Alvarado M

AU: Saunders C

AU: Eiermann W

AU: Metaxas M

AU: Sperk E

AU: Sütterlin M

AU: Brown D

AU: Esserman L

AU: Roncadin M

AU: Thompson A

AU: Dewar JA

AU: Holtveg HM

AU: Pigorsch S

AU: Falzon M

AU: Harris E

AU: Matthews A

AU: Brew-Graves C

AU: Potyka I

AU: Corica T

AU: Williams NR

AU: Baum M

TI: Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer: 5-year results for local control and overall survival from the TARGIT-A randomised trial.

SO: Lancet

YR: 2014

VL: 383

NO: 9917

PG: 603-13

PM: PUBMED 24224997

XR: EMBASE 2014112136

PT: Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Breast Neoplasms [mortality] [radiotherapy] [surgery]; Carcinoma, Ductal, Breast [mortality] [radiotherapy] [surgery]; Intraoperative Care [methods] [mortality]; Kaplan-Meier Estimate; Mastectomy, Segmental [methods] [mortality]; Neoplasm Recurrence, Local [mortality] [prevention & control]; Radiotherapy [methods] [mortality]; Treatment Outcome; Aged[checkword]; Female[checkword]; Humans[checkword]; Middle Aged[checkword]; adult; article; *breast carcinoma/rt [Radiotherapy]; *breast carcinoma/su [Surgery]; *cancer control; cancer mortality; cancer radiotherapy; cancer recurrence; cancer


risk; cancer surgery; controlled study; *external beam radiotherapy; female; follow up; human; *intraoperative radiotherapy; major clinical study; middle aged; multicenter study; outcome assessment; *overall survival; partial mastectomy; priority journal; radiation dose; radiation injury/co [Complication]; radiotherapy equipment; randomized controlled trial; skin disease/co [Complication]; *targeted intraoperative radiotherapy; *whole breast radiotherapy; wound/co [Complication]

DOI: 10.1016/S0140-6736(13)61950-9

AB: BACKGROUND: The TARGIT-A trial compared risk-adapted radiotherapy using single-dose targeted intraoperative radiotherapy (TARGIT) versus fractionated external beam radiotherapy (EBRT) for breast cancer. We report 5-year results for local recurrence and the first analysis of overall survival. **METHODS:** TARGIT-A was a randomised, non-inferiority trial. Women aged 45 years and older with invasive ductal carcinoma were enrolled and randomly assigned in a 1:1 ratio to receive TARGIT or whole-breast EBRT, with blocks stratified by centre and by timing of delivery of targeted intraoperative radiotherapy: randomisation occurred either before lumpectomy (prepathology stratum, TARGIT concurrent with lumpectomy) or after lumpectomy (postpathology stratum, TARGIT given subsequently by reopening the wound). Patients in the TARGIT group received supplemental EBRT (excluding a boost) if unforeseen adverse features were detected on final pathology, thus radiotherapy was risk-adapted. The primary outcome was absolute difference in local recurrence in the conserved breast, with a prespecified non-inferiority margin of 2.5% at 5 years; prespecified analyses included outcomes as per timing of randomisation in relation to lumpectomy. Secondary outcomes included complications and mortality. This study is registered with ClinicalTrials.gov, number NCT00983684. **FINDINGS:** Patients were enrolled at 33 centres in 11 countries, between March 24, 2000, and June 25, 2012. 1721 patients were randomised to TARGIT and 1730 to EBRT. Supplemental EBRT after TARGIT was necessary in 15.2% [239 of 1571] of patients who received TARGIT (21.6% prepathology, 3.6% postpathology). 3451 patients had a median follow-up of 2 years and 5 months (IQR 12-52 months), 2020 of 4 years, and 1222 of 5 years. The 5-year risk for local recurrence in the conserved breast was 3.3% (95% CI 2.1-5.1) for TARGIT versus 1.3% (0.7-2.5) for EBRT ($p=0.042$). TARGIT concurrently with lumpectomy (prepathology, $n=2298$) had much the same results as EBRT: 2.1% (1.1-4.2) versus 1.1% (0.5-2.5; $p=0.31$). With delayed TARGIT (postpathology, $n=1153$) the between-group difference was larger than 2.5% (TARGIT 5.4% [3.0-9.7] vs EBRT 1.7% [0.6-4.9]; $p=0.069$). Overall, breast cancer mortality was much the same between groups (2.6% [1.5-4.3] for TARGIT vs 1.9% [1.1-3.2] for EBRT; $p=0.56$) but there were significantly fewer non-breast-cancer deaths with TARGIT (1.4% [0.8-2.5] vs 3.5% [2.3-5.2]; $p=0.0086$), attributable to fewer deaths from cardiovascular causes and other cancers. Overall mortality was 3.9% (2.7-5.8) for TARGIT versus 5.3% (3.9-7.3) for EBRT ($p=0.099$). Wound-related complications were much the same between groups but grade 3 or 4 skin complications were significantly reduced with TARGIT (four of 1720 vs 13 of 1731, $p=0.029$). **INTERPRETATION:** TARGIT concurrent with lumpectomy within a risk-adapted approach should be considered as an option for eligible patients with breast cancer carefully selected as per the TARGIT-A trial protocol, as an alternative to postoperative EBRT. **FUNDING:** University College London Hospitals (UCLH)/UCL Comprehensive Biomedical Research Centre, UCLH Charities, National Institute for Health Research Health Technology Assessment programme, Ninewells Cancer Campaign, National

Health and Medical Research Council, and German Federal Ministry of Education and Research.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/887/CN-00977887/frame.html>

Record #13 of 370 

ID: CN-00979937

AU: Kirkham BW

AU: Wasko MC

AU: Hsia EC

AU: Fleischmann RM

AU: Genovese MC

AU: Matteson EL

AU: Liu H

AU: Rahman MU

TI: Effects of golimumab, an anti-tumour necrosis factor-alpha human monoclonal antibody, on lipids and markers of inflammation.

SO: Annals of the Rheumatic Diseases

YR: 2014

VL: 73

NO: 1

PG: 161-169

XR: EMBASE 2013775424

KY: adult; article; cardiovascular disease; cardiovascular risk; cholesterol blood level; clinical effectiveness; disease association; drug effect; drug efficacy; drug response; female; human; lipoprotein blood level; major clinical study; male; middle aged; phase 3 clinical trial (topic); priority journal; randomized controlled trial (topic); *rheumatoid arthritis/dt [Drug Therapy]; risk assessment; treatment duration; treatment outcome; *biological marker/ec [Endogenous Compound]; cholesterol/ec [Endogenous Compound]; *golimumab/ct [Clinical Trial]; *golimumab/cb [Drug Combination]; *golimumab/dt [Drug Therapy]; *golimumab/sc

[Subcutaneous Drug Administration]; high density lipoprotein/ec [Endogenous Compound]; interleukin 6/ec [Endogenous Compound]; interleukin 8/ec [Endogenous Compound]; *lipid/ec [Endogenous Compound]; low density lipoprotein/ec [Endogenous Compound]; methotrexate/ct [Clinical Trial]; methotrexate/cb [Drug Combination]; methotrexate/dt [Drug Therapy]; methotrexate/po [Oral Drug Administration]; placebo; stromelysin/ec [Endogenous Compound]; vasculotropin/ec [Endogenous Compound]

DOI: <http://dx.doi.org/10.1136/annrheumdis-2012-202089>

AB: Objectives To assess the effect of golimumab, with or without methotrexate (MTX), on serum lipids and inflammatory markers of cardiovascular disease (CVD) in patients with rheumatoid arthritis (RA) in two phase 3, randomised, placebo-controlled trials (GO-BEFORE and GO-FORWARD). Methods Patients in GO-BEFORE (n=637, MTX-naïve) and GO-FORWARD (n=444, MTX-inadequate response) were randomised to placebo+MTX, golimumab 100 mg +placebo, golimumab 50 mg+MTX, or golimumab 100 mg+MTX. Subcutaneous injections (placebo and golimumab) were given every 4 weeks. Patients with an insufficient response entered early escape at week 16 (GO-FORWARD) or 28 (GO-BEFORE). All placebo+MTX patients in GO-FORWARD crossed over to golimumab 50 mg+MTX at week 24. Changes from baseline to weeks 14 (GO-FORWARD) or 24 (GO-BEFORE), and 52 in serum lipid levels and inflammatory markers were assessed. Results At week 14 in the GO-FORWARD trial, total cholesterol (TC), high-density lipoprotein (HDL) and lowdensity lipoprotein (LDL) increased in golimumab+MTX patients versus MTX-only patients (16.00 vs 2.00 ($p<0.001$); 3.00 vs 0.00 ($p<0.05$); 8.00 vs 4.00 ($p<0.001$); respectively); favourable changes in LDL subfractions were only observed in golimumab-treated patients. At week 24 in GO-BEFORE, TC and LDL increased, and LDL subfractions improved in the MTX-only and golimumab+MTX groups. Inflammatory markers of CVD risk improved significantly with golimumab+MTX versus placebo+MTX in both studies and were generally maintained through week 52. Atherogenic indices were generally stable. Conclusions While TC and LDL levels increased mildly in RA patients receiving golimumab+MTX, atherogenic indices generally remained stable, favourable changes in LDL subfractions were observed, and inflammatory markers improved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/937/CN-00979937/frame.html>

Record #14 of 370



ID: CN-00968059

AU: Dubois B

AU: Tolosa E

AU: Katzenschlager R

AU: Emre M

AU: Lees AJ

AU: Schumann G

AU: Pourcher E

AU: Gray J

AU: Thomas G

AU: Swartz J

AU: Hsu T

AU: Moline ML

TI: Donepezil in Parkinson's disease dementia: a randomized, double-blind efficacy and safety study.

SO: Movement disorders

YR: 2014

VL: 27

NO: 10

PG: 1230-8

PM: PUBMED 22915447

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Analysis of Variance;Cholinesterase Inhibitors [therapeutic use];Dementia [complications] [drug therapy];Dose-Response Relationship, Drug;Double-Blind Method;Europe;Indans [therapeutic use];Parkinson Disease [complications] [drug therapy];Piperidines [therapeutic use];Psychiatric Status Rating Scales;Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1002/mds.25098

AB: Parkinson's disease dementia (PDD) is associated with cholinergic deficits. This report presents an efficacy and safety study of the acetylcholinesterase inhibitor donepezil hydrochloride in PDD. PDD patients (n = 550) were randomized to donepezil (5 or 10 mg) or placebo for 24 weeks. Coprimary end points were the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and Clinician's Interview-Based Impression of Change plus caregiver input (CIBIC+; global function). Secondary end points measured executive function, attention, activities of daily living (ADLs), and behavioral symptoms. Safety and tolerability

were assessed. ADAS-cog mean changes from baseline to week 24 (end point) were not significant for donepezil in the intent-to-treat population by the predefined statistical model (difference from placebo: -1.45, $P = .050$, for 5 mg; -1.45, $P = .076$, for 10 mg). Alternative ADAS-cog analysis, removing the treatment-by-country interaction term from the model, revealed significant, dose-dependent benefit with donepezil (difference from placebo: -2.08, $P = .002$, for 5 mg; -3.31, $P < .001$, for 10 mg). The 10-mg group, but not the 5-mg group, had significantly better CIBIC+ scores compared with placebo (3.7 vs 3.9, $P = .113$, for 5 mg; 3.6 vs 3.9, $P = .040$, for 10 mg). Secondary end points-Mini-Mental State Exam; Delis-Kaplan Executive Function System; Brief Test of Attention, representing cognitive functions particularly relevant to PDD-showed significant benefit for both donepezil doses ($P \leq .007$). There were no significant differences in ADLs or behavior. Adverse events were more common with donepezil but mostly mild/moderate in severity. Although the study did not achieve its predefined primary end points, it presents evidence suggesting that donepezil can improve cognition, executive function, and global status in PDD. Tolerability was consistent with the known safety profile of donepezil. © 2012 Movement Disorder Society.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/059/CN-00968059/frame.html>

Record #15 of 370



ID: CN-00913933

AU: Schmitt FA

AU: Saxton J

AU: Ferris SH

AU: Mackell J

AU: Sun Y

TI: Evaluation of an 8-item Severe Impairment Battery (SIB-8) vs. the full SIB in moderate to severe Alzheimer's disease patients participating in a donepezil study.

SO: International journal of clinical practice

YR: 2014

VL: 67

NO: 10

PG: 1050-6

PM: PUBMED 24073978

XR: EMBASE 2013619412

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [drug therapy];Analysis of Variance;Cognition Disorders [diagnosis];Double-Blind Method;Indans [administration & dosage];Neuropsychological Tests [standards];Nootropic Agents [administration & dosage];Piperidines [administration & dosage];Severity of Illness Index;Treatment Outcome;Humans[checkword];*Alzheimer disease/dt [Drug Therapy]; article; clinical article; clinical practice; controlled study; disease severity; dose response; drug effect; drug efficacy; drug megadose; female; functional assessment; human; instrument validation; intermethod comparison; internal consistency; male; mental performance; Mini Mental State Examination; patient assessment; priority journal; randomized controlled trial; *rating scale; *Severe Impairment Battery Scale; *donepezil/ct [Clinical Trial]; *donepezil/do [Drug Dose]; *donepezil/dt [Drug Therapy]

DOI: 10.1111/ijcp.12188

AB: AIM: The Severe Impairment Battery (SIB), a reliable cognitive measure for evaluating treatment response in advanced Alzheimer's disease (AD), takes approximately 20 min to administer. A recently derived 8-item version of the SIB - the SIB-8 - which takes about 3 min to administer, may represent a more convenient tool for use in clinical practice. The current analyses further explored the SIB-8 scale with respect to its validity and sensitivity. METHODS: A post hoc analysis was performed using data from a 24-week trial of donepezil 23 mg/day and 10 mg/day in > 1400 patients with moderate to severe AD [baseline Mini-Mental State Examination (MMSE) score 0-20]. Treatment effects on cognition (patterns of score change) were assessed using the full SIB and SIB-8 in the total study population and subgroups based on concomitant memantine use and baseline MMSE. Internal consistency/agreement and correlations between the SIB and SIB-8 and other clinical end points were evaluated. RESULTS: Assessment of score changes from baseline to week 24 with donepezil (23 or 10 mg/day) demonstrated comparable patterns of change when using the SIB-8 and the full SIB, despite inherent differences in the total score ranges for the two scales. Internal consistency/agreement between the full SIB and SIB-8 was good (Cronbach's alphas: 0.77-0.95). SIB-8 scores reliably correlated with SIB total scores ($r = 0.859$, baseline; $r = 0.900$, week 24; $p < 0.0001$), as well as MMSE scores ($r = 0.7163$, baseline; $r = 0.7963$, week 24; $p < 0.0001$). Scores on both SIB scales were moderately associated with functional measures at baseline and week 24. CONCLUSIONS: In this post hoc analysis, similar treatment effects were measured by the full SIB and the SIB-8. Very good internal consistency/agreement and strong correlations between the SIB and the more rapid and convenient SIB-8 indicate that the SIB-8 may be a useful and efficient clinical proxy for the full SIB in evaluating treatment response in patients with advanced AD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/933/CN-00913933/frame.html>

Record #16 of 370



ID: CN-00907133

AU: Cook C

AU: Learman K

AU: Showalter C

AU: Kabbaz V

AU: O'Halloran B

TI: Early use of thrust manipulation versus non-thrust manipulation: A randomized clinical trial.

SO: Manual therapy

YR: 2014

VL: 18

NO: 3

PG: 191-8

XR: EMBASE 2013289725

PT: Journal: Article

KY: adult; article; controlled study; equipoise; exercise; female; follow up; home care; hospital discharge; hospitalization; human; intermethod comparison; *low back pain/th [Therapy]; major clinical study; male; *manipulative medicine; *non thrust manipulation; numeric pain rating scale; Oswestry Disability Index; outcome assessment; pain assessment; priority journal; randomized controlled trial; rating scale; *thrust manipulation

CC: SR-BACK

DOI: 10.1016/j.math.2012.08.005

AB: The purpose of this study was to investigate the comparative effectiveness of early use of thrust (TM) and non-thrust manipulation (NTM) in sample of patients with mechanical low back pain (LBP). The randomized controlled trial included patients with mechanically reproducible LBP, >age 18-years who were randomized into two treatment groups. The main outcome measures were the Oswestry Disability Index (ODI) and a Numeric Pain Rating Scale (NPRS), with secondary measures of Rate of Recovery, total visits and days in care, and the work subscale of the Fears Avoidance Beliefs Questionnaire work subscale (FABQ-w). A two-way mixed model MANCOVA was used to compare ODI and pain, at baseline, after visit 2, and at discharge and total visits, days in care, and rate of recovery (while controlling for patient expectations and clinical equipoise). A total of 149 subjects completed the trial and received

care over an average of 35 days. There were no significant differences between TM and NTM at the second visit follow-up or at discharge with any of the outcomes categories. Personal equipoise was significantly associated with ODI and pain. The findings suggest that there is no difference between early use of TM or NTM, and secondarily, that personal equipoise affects study outcome. Within-groups changes were significant for both groups. 2012 Elsevier Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/133/CN-00907133/frame.html>

Record #17 of 370



ID: CN-00961438

AU: Basnet A

AU: Butler S

AU: Honore PH

AU: Butler M

AU: Gordh TE

AU: Kristensen K

AU: Bjerrum OJ

TI: Donepezil provides positive effects to patients treated with gabapentin for neuropathic pain: An exploratory study.

SO: Acta anaesthesiologica Scandinavica

YR: 2014

VL: 58

NO: 1

PG: 61-73

XR: EMBASE 2013798117

PT: Journal: Article

KY: add on therapy // adult // aged // analgesia // article // clinical article // computer program // confusion/si [Side Effect] // constipation/si [Side Effect] // controlled study // diarrhea/si [Side Effect] // disease duration // dizziness/si [Side Effect] // drug dose titration // drug effect // drug efficacy // drug megadose // drug tolerability // drug withdrawal //

exploratory research // female // human // loading drug dose // male // middle aged // monotherapy // mood disorder/si [Side Effect] // muscle cramp/si [Side Effect] // nausea and vomiting/si [Side Effect] // *neuropathic pain/dm [Disease Management] // *neuropathic pain/dt [Drug Therapy] // open study // pain assessment // posttraumatic pain/dm [Disease Management] // posttraumatic pain/dt [Drug Therapy] // priority journal // psychological well being // quality of life // questionnaire // randomized controlled trial // somnolence/si [Side Effect] // treatment duration // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/cb [Drug Combination] // *donepezil/cm [Drug Comparison] // *donepezil/dt [Drug Therapy] // *gabapentin/ae [Adverse Drug Reaction] // *gabapentin/ct [Clinical Trial] // *gabapentin/cb [Drug Combination] // *gabapentin/do [Drug Dose] // *gabapentin/dt [Drug Therapy] // venlafaxine/ct [Clinical Trial] // venlafaxine/cb [Drug Combination] // venlafaxine/cm [Drug Comparison] // venlafaxine/dt [Drug Therapy]

DOI: 10.1111/aas.12218

AB: Background The first-line medication gabapentin and the acetylcholinesterase inhibitor donepezil represent a new promising combination to improve treatment outcomes for patients with severe neuropathic pain. The drugs have previously shown synergism following co-administration in nerve-injured rats. Methods The clinical relevance of adding donepezil to existing gabapentin treatment in patients with post-traumatic neuropathic pain was explored in this open-label study. The study comprised two consecutive periods of minimum 6 weeks: (1) titration of gabapentin to the highest tolerable dose or maximum 2400 mg daily, and (2) addition of donepezil 5 mg once daily to the fixed gabapentin dose. Efficacy and tolerability were assessed by ratings of pain intensity, questionnaires for pain and health-related quality of life, and reporting of adverse events. Pain scores were also analysed using mixed-effects analysis with the software NONMEM to account for intersubject variability. Results Eight patients commenced treatment with donepezil, of which two withdrew because of adverse events. Addition of donepezil resulted in clinically relevant reductions of pain (> 11 units on a 0-100 scale) and improved mental wellness in three of six patients. The remaining three patients had no obvious supplemental effect. Mixed-effects analysis revealed that pain scores were significantly lower during co-administration ($P < 0.0001$ combination vs. monotherapy). Conclusion Donepezil may provide additional analgesia to neuropathic pain patients with insufficient pain relief from gabapentin as monotherapy. The promising results support controlled clinical trials of the drug combination. The usefulness of mixed-effects analysis in small-scale trials and/or for data with high intersubject variability was also demonstrated. 2013 The Acta Anaesthesiologica Scandinavica Foundation. Published by John Wiley & Sons Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/438/CN-00961438/frame.html>

ID: CN-00961449

AU: Dysken MW

AU: Guarino PD

AU: Vertrees JE

AU: Asthana S

AU: Sano M

AU: Llorente M

AU: Pallaki M

AU: Love S

AU: Schellenberg GD

AU: McCarten JR

AU: Malphurs J

AU: Prieto S

AU: Chen P

AU: Loreck DJ

AU: Carney S

AU: Trapp G

AU: Bakshi RS

AU: Mintzer JE

AU: Heidebrink JL

AU: Vidal-Cardona A

AU: Arroyo LM

AU: Cruz AR

AU: Kowall NW

AU: Chopra MP

AU: Craft S

AU: Thielke S

AU: Turvey CL

AU: Woodman C

AU: Monnell KA

AU: Gordon K

AU: Tomaska J

AU: Vatassery G

TI: Vitamin e and memantine in Alzheimer's disease: Clinical trial methods and baseline data.

SO: Alzheimer's & dementia

YR: 2014

VL: 10

NO: 1

PG: 36-44

XR: EMBASE 2013818818

PT: Journal: Article

KY: adult // aged // *Alzheimer disease/dt [Drug Therapy] // Alzheimer Disease Assessment Scale // article // controlled study // daily life activity // disease course // disease severity // double blind procedure // female // follow up // food and drug administration // human // major clinical study // male // middle aged // Mini Mental State Examination // multicenter study // priority journal // randomized controlled trial // scoring system // very elderly // *alpha tocopherol/ct [Clinical Trial] // *alpha tocopherol/cb [Drug Combination] // *alpha tocopherol/dt [Drug Therapy] // *alpha tocopherol/po [Oral Drug Administration] // donepezil/cb [Drug Combination] // donepezil/dt [Drug Therapy] // galantamine/cb [Drug Combination] // galantamine/dt [Drug Therapy] // *memantine/ct [Clinical Trial] // *memantine/cb [Drug Combination] // *memantine/dt [Drug Therapy] // placebo // rivastigmine/cb [Drug Combination] // rivastigmine/dt [Drug Therapy]

CC: SR-DEMENTIA

DOI: 10.1016/j.jalz.2013.01.014

AB: Background: Alzheimer's disease (AD) has been associated with both oxidative stress and excessive glutamate activity. A clinical trial was designed to compare the effectiveness of (i) alpha-tocopherol, a vitamin E antioxidant; (ii) memantine (Namenda), an N-methyl-D-aspartate antagonist; (iii) their combination; and (iv) placebo in delaying clinical progression in AD. Methods: The Veterans Affairs Cooperative Studies Program initiated a multicenter, randomized, double-blind, placebo-controlled trial in August 2007, with enrollment through March 2012 and follow-up continuing through September 2012. Participants with mild-to-

moderate AD who were taking an acetylcholinesterase inhibitor were assigned randomly to 2000 IU/day of alpha-tocopherol, 20 mg/day memantine, 2000 IU/day alpha-tocopherol plus 20 mg/day memantine, or placebo. The primary outcome for the study is the Alzheimer's Disease Cooperative Study/Activities of Daily Living Inventory. Secondary outcome measures include the Mini-Mental State Examination; the Alzheimer's Disease Assessment Scale, cognitive portion; the Dependence Scale; the Neuropsychiatric Inventory; and the Caregiver Activity Survey. Patient follow-up ranged from 6 months to 4 years. Results: A total of 613 participants were randomized. The majority of the patients were male (97%) and white (86%), with a mean age of 79 years. The mean Alzheimer's Disease Cooperative Study/Activities of Daily Living Inventory score at entry was 57 and the mean Mini-Mental State Examination score at entry was 21. Conclusion: This large multicenter trial will address the unanswered question of the long-term safety and effectiveness of alpha-tocopherol, memantine, and their combination in patients with mild-to-moderate AD taking an acetylcholinesterase inhibitor. The results are expected in early 2013. 2014 The Alzheimer's Association. All rights reserved.

US: <http://onlinelibrary.wiley.com/doi/10.1002/1449/449/CN-00961449/frame.html>

Record #19 of 370



ID: CN-00959471

AU: Cook C

AU: Learman K

AU: Houghton S

AU: Showalter C

AU: O'Halloran B

TI: The addition of cervical unilateral posterior-anterior mobilisation in the treatment of patients with shoulder impingement syndrome: A randomised clinical trial.

SO: Manual therapy

YR: 2014

VL: 19

NO: 1

PG: 18-24

XR: EMBASE 2014011496

PT: Journal: Article

KY: article // *cervical unilateral posterior anterior mobilisation // clinical article // controlled study // convalescence // disability // evidence based practice // female // human // male // *manipulative medicine // named inventories, questionnaires and rating scales // *neck manual therapy // pain // patient selection // priority journal // Quick Disabilities of the Shoulder and Hand Questionnaire // randomized controlled trial // *shoulder impingement syndrome // single blind procedure // symptom

DOI: 10.1016/j.math.2013.05.007

AB: Shoulder impingement syndrome (SIS) is a complex, multi-factorial problem that is treated with a variety of different conservative options. One conservative option that has shown effectiveness is manual therapy to the thoracic spine. Another option, manual therapy to the cervical spine, has been studied only once with good results, evaluating short-term outcomes, in a small sample size. The purpose of this study was to investigate the benefit of neck manual therapy for patients with SIS. The study was a randomised, single blinded, clinical trial where both groups received pragmatic, evidence-based treatment to the shoulder and one group received neck manual therapy. Subjects with neck pain were excluded from the study. Comparative pain, disability, rate of recovery and patient acceptable symptom state (PASS) measures were analyzed on the 68 subjects seen over an average of 56.1 days (standard deviation (SD). = 55.4). Eighty-six percent of the sample reported an acceptable change on the PASS at discharge. There were no between-groups differences in those who did or did not receive neck manual therapy; however, both groups demonstrated significant within-groups improvements. On average both groups improved 59.7% (SD. = 25.1) for pain and 53.5% (SD. = 40.2) for the Quick Disabilities of the Shoulder and Hand Questionnaire (QuickDASH) from baseline. This study found no value when neck manual therapy was added to the treatment of SIS. Reasons may include the lack of therapeutic dosage provided for the manual therapy approach or the lack of benefit to treating the neck in subjects with SIS who do not have concomitant neck problems. 2013 Elsevier Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/471/CN-00959471/frame.html>

Record #20 of 370



ID: CN-00872976

AU: Apostolova LG

AU: Babakchanian S

AU: Hwang KS

AU: Green AE

AU: Zlatev D

AU: Chou YY

AU: DeCarli C

AU: Jack CR

AU: Petersen RC

AU: Aisen PS

AU: Cummings JL

AU: Toga AW

AU: Thompson PM

TI: Ventricular enlargement and its clinical correlates in the imaging cohort from the ADCS MCI donepezil/vitamin E study.

SO: Alzheimer disease and associated disorders

YR: 2013

VL: 27

NO: 2

PG: 174-81

PM: PUBMED 23694947

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Activities of Daily Living;Alzheimer Disease [pathology] [prevention & control];Cerebral Ventricles [pathology];Cholinesterase Inhibitors [administration & dosage];Disease Progression;Double-Blind Method;Drug Therapy, Combination;Image Interpretation, Computer-Assisted;Indans [administration & dosage];Magnetic Resonance Imaging;Mild Cognitive Impairment [drug therapy] [pathology];Piperidines [administration & dosage];Vitamin E [administration & dosage];Vitamins [administration & dosage];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-DEMENTIA

DOI: 10.1097/WAD.0b013e3182677b3d

AB: We analyzed the baseline and 3-year T1-weighted magnetic resonance imaging data of 110 amnesic mild cognitive impairment (MCI) participants with minimal hippocampal atrophy at baseline from the Alzheimer's Disease Cooperative Study group MCI Donepezil/Vitamin E trial. Forty-six subjects converted to Alzheimer disease (AD) (MCIc), whereas 64 remained stable

(MCInc). We used the radial distance technique to examine the differences in lateral ventricle shape and size between MCInc and MCInc and the associations between ventricular enlargement and cognitive decline. MCInc group had significantly larger frontal and right body/occipital horns relative to MCInc at baseline and significantly larger bilateral frontal, body/occipital, and left temporal horns at follow-up. Global cognitive decline measured with AD Assessment scale cognitive subscale and Mini-Mental State Examination and decline in activities of daily living (ADL) were associated with posterior lateral ventricle enlargement. Decline in AD Assessment scale cognitive subscale and ADL were associated with left temporal and decline in Mini-Mental State Examination with right temporal horn enlargement. After correction for baseline hippocampal volume, decline in ADL showed a significant association with right frontal horn enlargement. Executive decline was associated with right frontal and left temporal horn enlargement.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/976/CN-00872976/frame.html>

Record #21 of 370



ID: CN-00865696

AU: Qasmi MN

AU: Khan U

AU: Abdul H

AU: Halima N

AU: Shahab U

AU: Mohiuddin E

TI: Clinical evaluation of herbal medicine for essential hypertension

SO: Journal of medicinal plants research

YR: 2013

VL: 6


NO: 25

PG: 4189-92

CC: SR-HTN: SR-COMPMED

DOI: 10.5897/JMPR12.025

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/696/CN-00865696/frame.html>

Record #22 of 370 

ID: CN-00863276

AU: Miao YC

AU: Tian JZ

AU: Shi J

AU: Mao M

TI: Effects of Chinese medicine for tonifying the kidney and resolving phlegm and blood stasis in treating patients with amnesic mild cognitive impairment: a randomized, double-blind and parallel-controlled trial.

SO: Zhong xi yi jie he xue bao [Journal of Chinese integrative medicine]

YR: 2013

VL: 10

NO: 4

PG: 390-7

PM: PUBMED 22500712

PT: Journal Article; Randomized Controlled Trial; Research Support, U.S. Gov't, Non-P.H.S.

KY: Alzheimer Disease [drug therapy];Double-Blind Method;Drugs, Chinese Herbal [therapeutic use];Indans [therapeutic use];Mild Cognitive Impairment [drug therapy];Phytotherapy;Piperidines [therapeutic use];Treatment Outcome;Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA: SR-COMP MED

AB: BACKGROUND: It is important to detect and prevent Alzheimer disease (AD) at its early stage. Constituting the early stage sign of AD, amnesic mild cognitive impairment (aMCI) has drawn much attention. Studies have shown that donepezil could reduce the AD assessment scale-cognitive subscale (ADAS-Cog) score in MCI patients and improve the patient's attention and speed of response; however, it also has many side effects. Therefore, the authors aim to explore the effects of Chinese herbal medicine for treating aMCI. OBJECTIVE: To explore the

clinical efficacy and safety of Chinese medicine for tonifying the kidney, and resolving phlegm and blood stasis in the treatment of aMCI. DESIGN, SETTING, PARTICIPANTS AND INTERVENTIONS: This clinical trial used randomized, double-blind, double-dummy and parallel-controlled design. According to the randomized, double-blind principle, some aMCI patients were randomly divided into Chinese medicine group and donepezil group. Other patients who did not receive any treatment were enrolled as the control. Patients in the Chinese medicine group received oral administration of Chinese medicine, 1 bag/dose, two doses per day, while patients in the donepezil group received donepezil hydrochloride, 5mg/day. Twelve weeks were allocated as the trial period. MAIN OUTCOME MEASURES: After 12 weeks, the Chinese medicine group patients, the donepezil group patients and those patients who did not receive any treatment were accessed using the scores of ADAS-Cog and mini-mental status examination (MMSE). RESULTS: The ADAS-Cog and MMSE scores of the Chinese medicine group and the donepezil group were both improved from baseline ($P=0.001$, $P=0.000$), but the non-treatment group showed no change from baseline ($P=0.151$, $P=0.125$); furthermore, there was no significant difference between the Chinese medicine group and the donepezil group. The attention function of the Chinese medicine group was better than baseline ($P=0.015$), but no change was seen in the donepezil group ($P=0.085$) at the 12th week. Safety data showed that the occurrence of insomnia, nausea and diarrhea was greater in the donepezil group than in the Chinese medicine group ($P=0.002$, $P=0.005$, $P=0.000$), and both treatments had no influence in participants' vital signs and laboratory examination results. CONCLUSION: Both Chinese medicine and donepezil can improve global cognition in patients with aMCI after 12 weeks of treatment. Chinese medicine can also improve attention function and some clinical symptoms in patients with aMCI. Furthermore, Chinese medicine is safe for aMCI patients. Further study is necessary to explore the long-term effect of Chinese medicine for aMCI.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/276/CN-00863276/frame.html>

Record #23 of 370



ID: CN-00914335

AU: Gadiko C

AU: Koundinya Tippabhotla S

AU: Thota S

AU: Battula R

AU: Khan MS

AU: Vobalaboina V

TI: A randomized, crossover, single-dose bioequivalence study of two extended-release tablets of donepezil 23 mg in healthy human volunteers under fasting and fed states.

SO: Scientia pharmaceutica

YR: 2013

VL: 81

NO: 3

PG: 777-91

XR: EMBASE 2013604112


PT: Journal: Article

KY: adult // anisocoria/si [Side Effect] // area under the curve // article // asthenia/si [Side Effect] // backache/si [Side Effect] // *bioequivalence // blood sampling // crossover procedure // diet restriction // dietary intake // drug bioavailability // drug safety // drug withdrawal // female // headache/si [Side Effect] // herpetic stomatitis/si [Side Effect] // human // human experiment // male // mastitis/si [Side Effect] // maximum plasma concentration // muscle spasm/si [Side Effect] // mydriasis/si [Side Effect] // nausea/si [Side Effect] // neck pain/si [Side Effect] // neutrophil count // normal human // paresthesia/si [Side Effect] // photophobia/si [Side Effect] // plasma concentration-time curve // randomized controlled trial // side effect/si [Side Effect] // single drug dose // time to maximum plasma concentration // vomiting/si [Side Effect] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/cr [Drug Concentration] // *donepezil/pk [Pharmacokinetics]

DOI: 10.3797/scipharm.1302-13

AB: To assess the bioequivalence of two extended-release tablets of donepezil 23 mg, open label, randomized, single-dose, two-sequence, two-period cross-over studies under fasting (n=74) and fed (n=94) conditions in healthy adult human volunteers were conducted. Subjects were randomized to either of the two treatment arms (test or reference) separated by a washout period of 28 days. Blood samples were collected up to 72 h post-dose and plasma samples were analyzed for donepezil using a validated LC-MS/MS method. Pharmacokinetic parameters were derived using a non-compartmental approach. Bioequivalence was evaluated in 69 subjects in the fasting study, and 71 subjects in the fed study. In the fasting study, the 90% CI of C_{max} and AUC₀₋₇₂ were 82.50-90.10 and 92.38-98.60, respectively. Corresponding values in the fed study were 91.82-98.05 and 97.27-100.27. Based on the results, the test product (donepezil) met the US regulatory criteria of bioequivalence relative to the reference product (Aricept) under both fasting and fed conditions. Gadiko et al.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/335/CN-00914335/frame.html>

Record #24 of 370 

ID: CN-00911793

AU: Kano O

AU: Ito H

AU: Takazawa T

AU: Kawase Y

AU: Murata K

AU: Iwamoto K

AU: Nagaoka T

AU: Hirayama T

AU: Miura K

AU: Nagata R

AU: Kiyozuka T

AU: Aoyagi J

AU: Sato R

AU: Eguchi T

AU: Ikeda K

AU: Iwasaki Y

TI: Clinically meaningful treatment responses after switching to galantamine and with addition of memantine in patients with Alzheimer's disease receiving donepezil.

SO: Neuropsychiatric disease and treatment

YR: 2013

VL: 9

PG: 259-65

XR: EMBASE 2013130356

PT: Journal: Article

KY: aged // agitation // *Alzheimer disease/dt [Drug Therapy] // article // caregiver // cognition // Cohen Mansfield agitation inventory // controlled study // disability assessment for dementia // disease severity // drug dose comparison // drug dose increase // drug dose titration // drug efficacy // drug safety // drug substitution // drug withdrawal // female // human // major clinical study // male // mental function impairment scale // Mini Mental State Examination // neuropsychiatric inventory score // open study // randomized controlled trial // rating scale // treatment duration // *treatment response // *donepezil/ct [Clinical Trial] // *donepezil/cb [Drug Combination] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy] // *galantamine/ct [Clinical Trial] // *galantamine/dt [Drug Therapy] // *memantine/ct [Clinical Trial] // *memantine/cb [Drug Combination] // *memantine/dt [Drug Therapy]

DOI: 10.2147/NDT.S40682

AB: Clinical trials have shown the benefits of acetylcholinesterase inhibitors, such as donepezil and galantamine, and an N-methyl-d-aspartate receptor antagonist, memantine, in patients with Alzheimer's disease (AD). However, little is known regarding the effects of switching from donepezil 5 mg/day to galantamine 16 or 24 mg/day, or regarding the effects of adding memantine to established therapy compared with increasing the dose of donepezil. This report discusses two studies conducted to evaluate treatment with galantamine and memantine with respect to cognitive benefits and caregiver evaluations in patients with AD receiving donepezil 5 mg/day for more than 6 months. Patients with mild or moderate AD (scores 10-22 on the Mini-Mental State Examination) were enrolled in the Galantamine Switch study and switched to galantamine (maximum doses 16 mg versus 24 mg). Patients with moderate to severe AD (MiniMental State Examination scores 3-14) were enrolled in the Donepezil Increase versus Additional Memantine study and either had their donepezil dose increased to 10 mg/day or memantine 20 mg/day added to their existing donepezil dose. Patients received the study treatment for 28 weeks and their Disability Assessment for Dementia, Mental Function Impairment Scale, Cohen-Mansfield Agitation Inventory, and Neuropsychiatric Inventory scores were assessed with assistance from their caregivers. For the Galantamine Switch study after 8 weeks, agitation evaluated by the Cohen-Mansfeld Agitation Inventory improved in both the 16 mg and 24 mg groups compared with baseline. However, there were no significant differences between the two galantamine groups. Agitation was also less in patients in the additional memantine group than in the donepezil increase group. In summary, switching to galantamine from donepezil and addition of memantine in patients with AD receiving donepezil were both safe and meaningful treatment options, and particularly efficacious for suppression of agitation. 2013 Kano et al, publisher and licensee Dove Medical Press Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/793/CN-00911793/frame.html>

ID: CN-00905303

AU: Chen J

AU: Lu Z

AU: Zhang M

AU: Zhang J

AU: Ni X

AU: Jiang X

AU: Xu H

AU: Heeramun-Aubeeluck A

AU: Hu Q

AU: Jin H

AU: Davis JM

TI: A randomized, 4-week double-blind placebo control study on the efficacy of donepezil augmentation of lithium for treatment of acute mania.

SO: Neuropsychiatric disease and treatment

YR: 2013

VL: 9

PG: 839-45

XR: EMBASE 2013386588

PT: Journal: Article

KY: adult // aged // article // bipolar disorder // clinical article // constipation/si [Side Effect] // controlled study // diarrhea/si [Side Effect] // disease classification // disease severity // double blind procedure // drug blood level // drug dose increase // drug dose titration // drug efficacy // drug induced headache/si [Side Effect] // drug safety // female // human // lethargy/si [Side Effect] // liver function // male // *mania/dt [Drug Therapy] // myoclonus/si [Side Effect] // nausea/si [Side Effect] // pruritus/si [Side Effect] // randomized controlled trial // side effect/si [Side Effect] // tachycardia/si [Side Effect] // taste disorder/si [Side Effect] // treatment duration // treatment response // weight reduction // xerostomia/si [Side Effect] // clonazepam/cm [Drug Comparison] // clonazepam/dt [Drug Therapy] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/cb [Drug Combination] // *donepezil/cm [Drug Comparison] // *donepezil/cr [Drug Concentration] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy] // *donepezil/po [Oral Drug Administration] //

*lithium salt/ct [Clinical Trial] // *lithium salt/cb [Drug Combination] // *lithium salt/cr [Drug Concentration] // *lithium salt/dt [Drug Therapy] // placebo

CC: SR-DEPRESSN

DOI: 10.2147/NDT.S40503

AB: Introduction: A significant number of mania patients fail to respond to current pharmacotherapy, thereby there is need for novel augmentation strategies. The results of some early studies showed the effectiveness of cholinomimetics in the treatment of mania. One open case series suggested the efficacy of donepezil in the treatment of bipolar disorder. Our aim was to explore whether an oral cholinesterase inhibitor, donepezil, administered during a 4-week treatment period, would benefit patients with acute mania. Methods: We conducted a 4-week double-blind, placebo-controlled trial of donepezil as an adjunctive treatment to lithium in patients with acute mania. Eligible subjects were randomly assigned to receive donepezil or placebo in addition to lithium. Donepezil was started at 5 mg/day, and increased to 10 mg/day in the first week. Patients were rated with the Young Mania Rating Scale (YMRS) and Brief Psychiatric Rating Scale (BPRS) at baseline, day 1, week 1, week 2, and week 4. Results: Out of the 30 patients who were enrolled, 15 were on donepezil and 15 were on placebo. All patients completed the 4-week trial. On the first day, there was a difference of 1.97 units on the psychomotor symptoms scale of the YMRS in the donepezil group as compared to the placebo group ($t = 2.39$, $P = 0.02$). There was a difference of 0.57 units ($t = 2.09$, $P = 0.04$) in the speech item and a difference of 0.29 units in the sexual interest item ($t = 2.11$, $P = 0.04$) in the donepezil group as compared to the placebo group. The total YMRS difference on the first day approached the conventional significance level (1.97 units, $t = 1.84$, $P = 0.07$). Over the course of 4 weeks, we failed to find that donepezil produced any significant difference in the YMRS (6.71 units difference, $t = -1.44$, $P = 0.16$) or the BPRS scale (1.29 units difference, $t = -0.33$, $P = 0.75$) as compared to placebo. Ten subjects (66.67%) in both groups met the criteria for clinical response (Fisher's exact $P = 1.00$). Five subjects (33.33%) in the donepezil group met the criteria for clinical remission while nine subjects (60.00%) in the placebo group met the remission criteria (Fisher's exact $P = 0.27$). Conclusion: Use of the oral anticholinergic donepezil had some benefit in the augmentation of lithium treatment on the first day, but did not provide any significant benefits in the long-term. 2013 Chen et al, publisher and licensee Dove Medical Press Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/303/CN-00905303/frame.html>

Record #26 of 370



ID: CN-00908032

AU: Ferris S

AU: Cummings J

AU: Christensen D

AU: Doody R

AU: Farlow M

AU: Sabbagh M

AU: Liu L

AU: MacKell J

AU: Fain R

TI: Effects of donepezil 23 mg on Severe Impairment Battery domains in patients with moderate to severe Alzheimer's disease: Evaluating the impact of baseline severity.

SO: Alzheimer's research & therapy

YR: 2013

VL: 5

NO: 1

XR: EMBASE 2013233982

PT: Journal: Article


KY: aged // *Alzheimer disease/dt [Drug Therapy] // article // attention // cognition // cohort analysis // controlled study // depth perception // descriptive research // disease severity // double blind procedure // drug dose comparison // female // human // language // major clinical study // male // memory // Mini Mental State Examination // parallel design // post hoc analysis // priority journal // randomized controlled trial // treatment response // *donepezil/ct [Clinical Trial] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy]

DOI: 10.1186/alzrt166

AB: Introduction. The US Food and Drug Administration approved a 23 mg daily dose of donepezil for treatment of moderate to severe Alzheimer's disease (AD) based on outcomes from a large trial comparing the 23 mg/day dose with the standard 10 mg/day dose. Results from this study indicated that after 24 weeks, donepezil 23 mg/day provided significant cognitive benefits over donepezil 10 mg/day, measured using the Severe Impairment Battery (SIB). In the analyses reported herein, we further characterize the range of cognitive domains impacted by treatment with donepezil 23 mg/day. Methods. A post hoc analysis was conducted using data from a 24-week, randomized, double-blind trial comparing donepezil 23 mg/day versus 10 mg/day in 1,467 patients with moderate to severe AD (baseline Mini-Mental State Examination (MMSE) score 0 to 20). Changes from baseline to week 24 in the nine SIB domain scores were analyzed in the intent-to-treat (ITT) population (baseline MMSE 0 to 20),

in patients with more severe baseline AD (MMSE 0 to 16), and in severity strata based on baseline MMSE scores (0 to 5, 6 to 10, 11 to 15, 16 to 20). Results: In the ITT population, changes in six of the nine SIB domains favored donepezil 23 mg/day over donepezil 10 mg/day. LS mean treatment differences were significant for the language, visuospatial ability, and construction domains. In the more advanced cohort of patients (MMSE 0 to 16 at baseline), LS mean treatment differences were statistically significant favoring donepezil 23 mg/day in five of the nine domains: language, memory, visuospatial ability, attention, and construction. Descriptive analysis of LS mean changes in SIB domain scores in the four baseline severity strata showed variable patterns of response; overall, cognitive benefits of donepezil 23 mg/day were greatest in patients with MMSE scores of 0 to 15. Conclusions: These results suggest that donepezil 23 mg/day provides benefits over 10 mg/day across a range of cognitive domains. The magnitude of benefit and domains impacted varied depending on the stage of AD; significant benefits with higher dose donepezil were most apparent at more advanced stages of AD and were most prominent in the language domain. 2013 Ferris et al.; licensee BioMed Central Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/032/CN-00908032/frame.html>

Record #27 of 370 

ID: CN-00911850

AU: Atri A

AU: Molinuevo JL

AU: Lemming O

AU: Wirth Y

AU: Pulte I

AU: Wilkinson D

TI: Memantine in patients with Alzheimer's disease receiving donepezil: New analyses of efficacy and safety for combination therapy.

SO: Alzheimer's research & therapy

YR: 2013

VL: 5

NO: 1

XR: EMBASE 2013104866

PT: Journal: Article

KY: aged // agitation // *Alzheimer disease/dt [Drug Therapy] // article // brain function // cognition // confusion/si [Side Effect] // controlled study // depression/si [Side Effect] // diarrhea/si [Side Effect] // dizziness/si [Side Effect] // double blind procedure // drug efficacy // drug safety // falling // female // human // major clinical study // male // Mini Mental State Examination // outcome assessment // priority journal // randomized controlled trial // rhinopharyngitis/si [Side Effect] // side effect/si [Side Effect] // treatment duration // treatment outcome // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/cb [Drug Combination] // *donepezil/dt [Drug Therapy] // galantamine/dt [Drug Therapy] // *memantine/ae [Adverse Drug Reaction] // *memantine/ct [Clinical Trial] // *memantine/cb [Drug Combination] // *memantine/dt [Drug Therapy] // placebo // rivastigmine/dt [Drug Therapy]

DOI: 10.1186/alzrt160

AB: Introduction. Memantine and cholinesterase inhibitors potentially offer additional benefits in Alzheimer's disease (AD) when used together. This study assessed the efficacy and safety of combination treatment with memantine added to stable donepezil in patients with moderate to severe AD, and in a subset with moderate AD. Methods. Post hoc meta-analyses of data combined from two 24-week, randomised, double-blind, placebo-controlled trials of memantine 20 mg/day versus placebo, added to a stable cholinesterase inhibitor, were conducted. Data were included for all patients receiving donepezil 10 mg/day with Mini-Mental State Examination (MMSE) scores < 20 (n = 510). Efficacy was assessed using measures of cognition, function, and global status. Furthermore, marked clinical worsening, defined as concurrent deterioration from baseline in the three main efficacy domains, and safety, measured by treatment-emergent adverse events, were assessed. Analyses were performed for patients with moderate to severe AD (MMSE 5-19; MOD-SEV subgroup), and also for patients with moderate AD (MMSE 10-19; MOD subgroup; n = 367). Results: At week 24, in the MOD-SEV subgroup, patients receiving memantine added to donepezil significantly outperformed those receiving placebo added to donepezil in measures of cognition ($P < 0.0001$), function ($P = 0.02$), and global status ($P = 0.010$), with standardised mean differences (SMDs) of 0.36, 0.21, and 0.23, respectively (all last observation carried forward). Similarly, in the MOD subgroup, significant benefits were observed for cognition ($P = 0.008$), function ($P = 0.04$) and global status ($P = 0.008$), with SMDs of 0.28, 0.21, and 0.28, respectively. Significantly fewer patients receiving memantine added to donepezil showed marked clinical worsening than those receiving placebo added to donepezil, in both subgroups (MOD-SEV: 8.7% versus 20.4%, $P = 0.0002$; MOD: 5.9% versus 15.0%, $P = 0.006$). The incidence of adverse events was similar between treatment groups. Conclusions: These results support and extend previous evidence that combination treatment with memantine added to stable donepezil in patients with moderate AD, and in those with moderate to severe AD, is associated with significant benefits in reducing 24-week decline in cognition, function and global status. Combination treatment produces substantially reduced rates of marked clinical worsening, has good safety and tolerability, and generates effect sizes that are both statistically significant and clinically meaningful. 2013 Atri et al.; licensee BioMed Central Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/850/CN-00911850/frame.html>

Record #28 of 370



ID: CN-00963955

AU: Pompeia S

AU: Gouveia JR

AU: Galduróz JC

TI: Acute mood effect of donepezil in young, healthy volunteers.

SO: Human psychopharmacology

YR: 2013

VL: 28

NO: 3

PG: 263-9

PM: PUBMED 23653426

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Affect [drug effects];Anxiety [prevention & control];Brain-Derived Neurotrophic Factor [drug effects] [metabolism];Cholinesterase Inhibitors [administration & dosage] [pharmacokinetics] [pharmacology];Cross-Over Studies;Dose-Response Relationship, Drug;Double-Blind Method;Indans [administration & dosage] [pharmacokinetics] [pharmacology];Piperidines [administration & dosage] [pharmacokinetics] [pharmacology];Questionnaires;Adult[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

DOI: 10.1002/hup.2319

AB: OBJECTIVE: Chronic use of the acetylcholinesterase inhibitor donepezil has been found to improve mood or to induce mania/hypomania in many neuropsychiatric patients with altered cholinergic and dopaminergic tone. Our aim was to determine whether acutely administered donepezil would alter mood in volunteers with no such alterations. METHODS: This investigation was a double-blind, crossover design study of 15 young, healthy male participants who were allocated in random order to three oral treatments: placebo and 5-mg and 7.5-mg donepezil (doses which exert clinical and acute cognitive effects without

considerable peripheral side effects). At the theoretical peak-plasma concentrations of donepezil, volunteers rated how they felt on validated questionnaires, which included various dimensions of subjective feelings. We also assessed changes in brain-derived neurotrophic factor (BDNF), which is increased by donepezil after chronic regimes and is related to modulation of mood. RESULTS: Donepezil significantly increased ratings of vigour and anxiety symptoms (medium effect sizes). No changes in bodily symptoms or BDNF were observed. CONCLUSIONS: Acute donepezil administration in participants with unaltered cholinergic and dopaminergic tone led to positive and negative changes in affect. These results call for further research on the direct mood effects of donepezil.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/955/CN-00963955/frame.html>

Record #29 of 370



ID: CN-00913709

AU: Sahu JK

AU: Gulati S

AU: Sapra S

AU: Arya R

AU: Chauhan S

AU: Chowdhury MR

AU: Gupta N

AU: Kabra M

AU: Gupta YK

AU: Dwivedi SN

AU: Kalra V

TI: Effectiveness and safety of donepezil in boys with fragile x syndrome: a double-blind, randomized, controlled pilot study.

SO: Journal of child neurology

YR: 2013

VL: 28

NO: 5

PG: 570-5

PM: PUBMED 22752489

XR: EMBASE 22752489

PT: Journal: Article

KY: Adolescent;Child Behavior Disorders [diagnosis] [drug therapy];Child Development Disorders, Pervasive [diagnosis] [drug therapy];Dose-Response Relationship, Drug;Double-Blind Method;Drug Administration Schedule;Fragile X Syndrome [diagnosis] [drug therapy];Indans [adverse effects] [therapeutic use];Intelligence [drug effects];Nootropic Agents [adverse effects] [therapeutic use];Personality Assessment;Pilot Projects;Piperidines [adverse effects] [therapeutic use];Stanford-Binet Test;Treatment Outcome;Child[checkword];Humans[checkword];Male[checkword]

DOI: 10.1177/0883073812449381

AB: The present study was designed as a 12-week, randomized, double-blind, placebo-controlled pilot study to evaluate the effectiveness and safety of donepezil in boys with fragile X syndrome. Twenty boys with fragile X syndrome were randomized to receive 12 weeks of treatment with either placebo or donepezil (2.5 mg daily for initial 4 weeks followed by 5 mg daily for next 8 weeks). The outcome measures included change in intelligence quotient scores on Stanford-Binet Intelligence Scale (Hindi adaptation by Kulshrestha), change in behavioral scores by Conners 3 Parent Rating Scale (Short) and Childhood Autism Rating Scale, safety, and tolerability of donepezil. The study failed to show significant difference in intelligence quotient and behavioral scales with donepezil therapy over 12 weeks. However, donepezil appeared to be safe and well tolerated.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/709/CN-00913709/frame.html>

Record #30 of 370



ID: CN-00915998

AU: Ikeda M

AU: Mori E

AU: Kosaka K

AU: Iseki E

AU: Hashimoto M

AU: Matsukawa N

AU: Matsuo K

AU: Nakagawa M

AU: Katayama S

AU: Higashi Y

AU: Yamada T

AU: Maruki Y

AU: Orimo S

AU: Yoshiiwa A

AU: Hanyu H

AU: Yokochi M

AU: Kimura T

AU: Mizoguchi K

AU: Nakanishi A

AU: Tsukamoto T

AU: Taniguchi N

AU: Okamoto K

AU: Kitamura T

AU: Nakano Y

AU: Kato T

AU: Shimada K

AU: Hiji M

AU: Yoshiyama Y

AU: Kitamura Y

AU: Takahashi S

AU: Akishita M

AU: Washimi Y

AU: Yamamoto Y

AU: Kobayashi M

AU: Udaka F

AU: Osaki Y

AU: Hino H

AU: Kanda T

AU: Kishimoto T

AU: Oguro H

AU: Matsuoka T

AU: Tsugu Y

AU: Fujii N

AU: Kawase Y

TI: Long-term safety and efficacy of donepezil in patients with dementia with lewy bodies:
Results from a 52-week, open-label, multicenter extension study.

SO: Dementia and geriatric cognitive disorders

YR: 2013

VL: 36

NO: 3-4

PG: 229-41

XR: EMBASE 2013608699

PT: Journal: Article

KY: acute pancreatitis/si [Side Effect] // aged // article // asphyxia/si [Side Effect] //
atrioventricular block/si [Side Effect] // blood pressure // bradycardia/si [Side Effect] //
caregiver burden // chronic drug administration // cognition // compression fracture/si [Side
Effect] // constipation/si [Side Effect] // controlled study // contusion/si [Side Effect] //
creatinine kinase blood level // decreased appetite/si [Side Effect] // dehydration/si [Side Effect]
// diarrhea/si [Side Effect] // *diffuse Lewy body disease/dt [Drug Therapy] // drug efficacy //
drug safety // falling // female // gastrointestinal symptom/si [Side Effect] // heart infarction/si
[Side Effect] // heart ventricle extrasystole/si [Side Effect] // hematuria/si [Side Effect] //
human // incidence // insomnia/si [Side Effect] // major clinical study // male // mental
disease/si [Side Effect] // Mini Mental State Examination // multicenter study //
neuropsychiatry // open study // parkinsonism/si [Side Effect] // pneumonia/si [Side Effect] //

priority journal // proteinuria/si [Side Effect] // QT prolongation/si [Side Effect] // randomized controlled trial // rhinopharyngitis/si [Side Effect] // side effect/si [Side Effect] // sinus bradycardia/si [Side Effect] // subarachnoid hemorrhage/si [Side Effect] // supraventricular premature beat/si [Side Effect] // symptom // treatment duration // treatment outcome // visual hallucination/si [Side Effect] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy] // placebo

DOI: 10.1159/000351672

AB: Background/Aims: To investigate the safety and efficacy of long-term administration (52 weeks) of donepezil in patients with dementia with Lewy bodies (DLB). Methods: This was a 52-week, multicenter, open-label extension study. Up to 8 weeks after the completion of the preceding randomized, placebo-controlled trial (RCT), patients started treatment with 3 mg of donepezil daily for 2 weeks, followed by 5 mg daily for the remaining 50 weeks. Cognitive function, behavioral and psychiatric symptoms, cognitive fluctuations, and caregiver burden were assessed using the Mini-Mental State Examination, Neuropsychiatric Inventory, Cognitive Fluctuation Inventory, and the Zarit Caregiver Burden Interview, respectively. Safety parameters were monitored throughout. Results: In total, 108 patients were enrolled in the study. Cognitive function and dementia-related behavioral symptoms, including cognitive fluctuations, were improved after the start of donepezil treatment, and improvement was maintained for 52 weeks. Reduction in caregiver burden observed in the preceding RCT returned to the baseline level at 52 weeks. There was no significant imbalance in the incidence of adverse events (AEs) by onset time, and delayed AE onset induced by the long-term administration of donepezil was unlikely to appear. Conclusion: The long-term administration of donepezil at 5 mg/day was well tolerated in patients with DLB and is expected to exhibit lasting effects, improving impaired cognitive function and psychiatric symptoms up to 52 weeks. 2013 S. Karger AG, Basel.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/998/CN-00915998/frame.html>

Record #31 of 370



ID: CN-00913979

AU: Song HR

AU: Woo YS

AU: Wang H-R

AU: Jun T-Y

AU: Bahk W-M

TI: Effect of the timing of acetylcholinesterase inhibitor ingestion on sleep.

SO: International clinical psychopharmacology

YR: 2013

VL: 28

NO: 6

PG: 346-8

XR: EMBASE 2013638506

PT: Journal: Article

KY: adult // aged // Alzheimer disease/dt [Drug Therapy] // article // body mass // Clinical Dementia Rating // controlled study // daytime somnolence // *dosage schedule comparison // evening dosage // female // human // major clinical study // male // Mini Mental State Examination // morning dosage // priority journal // randomized controlled trial // *sleep quality // sleep time // visual analog scale // *donepezil/dt [Drug Therapy] // *donepezil/po [Oral Drug Administration] // *donepezil/pd [Pharmacology] // *galantamine/dt [Drug Therapy]

DOI: 10.1097/YIC.0b013e328364f58d

AB: Many patients with Alzheimer's disease experience sleep disturbances, and donepezil is usually prescribed for night-time administration. However, increased acetylcholine is associated with cortical arousal. We evaluated whether subjective sleep quality differed according to the timing of medication administration. Ninety-two patients with mild to moderate Alzheimer's disease who had taken donepezil at night (n=54) or galantamine in the morning (n=38) were recruited for this study. Scores on the sleep visual analogue scale (VAS) for sleep quality and daytime drowsiness were obtained. The mean sleep-quality and daytime-drowsiness VAS scores of the donepezil and galantamine groups differed significantly at baseline (44.0+26.4 vs. 55.2+27.3, respectively; $P<0.001$ and 48.8+28.8 vs. 38.8+25.3, respectively; $P<0.001$). The patients taking donepezil were then randomly assigned to take donepezil in the morning (n=24) or at night (n=30). Eight weeks later, VAS scores also differed among the three groups ($P<0.001$ for both sleep quality and daytime drowsiness). The VAS scores of patients taking galantamine and donepezil in the morning were different from those taking donepezil at night at week 8. Significant changes in VAS scores emerged only in the group taking donepezil in the morning (4.6+26.5, $P=0.046$ for sleep quality; -7.1+26.1, $P<0.001$ for daytime drowsiness). These results suggest that taking acetylcholinesterase inhibitors in the morning can improve the sleep states of patients with Alzheimer's disease. 2013 Wolters Kluwer Health | Lippincott Williams & Wilkins.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/979/CN-00913979/frame.html>

Record #32 of 370



ID: CN-00913803

AU: Sawada H

AU: Oeda T

TI: Protocol for a randomised controlled trial: Efficacy of donepezil against psychosis in Parkinson's disease (EDAP).

SO: BMJ Open

YR: 2013

VL: 3

NO: 9

XR: EMBASE 2013640687

PT: Journal: Article

KY: aggression // article // clinical evaluation // clinical protocol // controlled study // cooperation // delusion // disease severity // double blind procedure // drug efficacy // emotional stress // hallucination // human // informed consent // intention to treat analysis // log rank test // multicenter study // outcome assessment // *Parkinson disease // Parkinson Psychosis Questionnaire // *psychosis/dt [Drug Therapy] // *psychosis/pc [Prevention] // questionnaire // randomized controlled trial // sleep disorder // social environment // Unified Parkinson Disease Rating Scale // wellbeing // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy] // placebo

DOI: 10.1136/bmjopen-2013-003533

AB: Introduction: Psychosis, including hallucinations and delusions, is one of the important non-motor problems in patients with Parkinson's disease (PD) and is possibly associated with cholinergic neuronal degeneration. The EDAP (Efficacy of Donepezil against Psychosis in PD) study will evaluate the efficacy of donepezil, a brain acetylcholine esterase inhibitor, for prevention of psychosis in PD. Methods and analysis: Psychosis is assessed every 4 weeks using the Parkinson Psychosis Questionnaire (PPQ) and patients with PD whose PPQ-B score (hallucinations) and PPQ-C score (delusions) have been zero for 8 weeks before enrolment are randomised to two arms: patients receiving donepezil hydrochloride or patients receiving placebo. The patients are then followed for 96 weeks. The primary outcome measure is the time to the event, defined as getting 2 points or more on the PPQ-B score or PPQ-C score, which is assessed using a survival time analysis. The hypothesis being tested is that donepezil prevents psychosis in patients with PD. Efficacy will be tested statistically using the intention-to-treat analysis including a log-rank test or Cox proportional hazard models. Secondary outcomes, such as changes of PPQ scores and Unified Parkinson's Disease Rating Scale scores from baseline will be assessed. Ethics and dissemination: Ethics approval was received from the Central Review Board of the National Hospital Organization, Tokyo, Japan. The trial was

declared and registered to the Pharmaceuticals and Medical Devices Agency(PMDA), Japan (No. 22-4018). All participants will receive a written informed consent that was approved by the Central Review. A completed written informed consent is required to enrol in the study. Severe adverse events will be monitored by investigators and in cases where a severe adverse event was previously unreported, it will be reported to the PMDA.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/803/CN-00913803/frame.html>

Record #33 of 370



ID: CN-00863286

AU: Solé-Padullés C

AU: Bartrés-Faz D

AU: Lladó A

AU: Bosch B

AU: Peña-Gómez C

AU: Castellví M

AU: Rami L

AU: Bargalló N

AU: Sánchez-Valle R

AU: Molinuevo JL

TI: Donepezil treatment stabilizes functional connectivity during resting state and brain activity during memory encoding in Alzheimer's disease.

SO: Journal of clinical psychopharmacology

YR: 2013

VL: 33

NO: 2

PG: 199-205

PM: PUBMED 23422370

XR: EMBASE 2013155790

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [physiopathology];Brain [drug effects] [physiopathology];Cholinesterase Inhibitors [pharmacology];Follow-Up Studies;Indans [pharmacology];Magnetic Resonance Imaging;Memory [drug effects];Piperidines [pharmacology];Time Factors;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword]

CC: SR-DEMENTIA

DOI: 10.1097/JCP.0b013e3182825bfd

AB: Previous studies with functional magnetic resonance imaging (fMRI) demonstrated a differential brain activity and connectivity after treatment with donepezil in Alzheimer's disease (AD) when compared to healthy elders. Importantly however, there are no available studies where the placebo or control group included comparable AD patients relative to the treated groups. Fifteen patients recently diagnosed of AD were randomized to treatment (n = 8) or to control group (n = 7); the former receiving daily treatment of donepezil during 3 months. At baseline and follow-up, both groups underwent resting-state as well as task-fMRI examinations, this latter assessing encoding of visual scenes. The treated group showed higher connectivity in areas of the default mode network, namely the right parahippocampal gyrus at follow-up resting-fMRI as compared to the control group. On the other hand, for the task-fMRI, the untreated AD group presented progressive increased activation in the left middle temporal gyrus and bilateral precuneus at the 3-month examination compared to baseline, whereas the treated group exhibited stable patterns of brain activity. Donepezil treatment is associated with stabilization of connectivity of medial temporal regions during resting state and of brain efficiency during a cognitive demand, on the whole reducing progressive dysfunctional reorganizations observed during the natural course of the disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/286/CN-00863286/frame.html>

Record #34 of 370



ID: CN-00908503

AU: Tariot PN

TI: Cessation of donepezil is associated with clinical decline in patients with moderate-to-severe Alzheimer's disease compared to continuation of donepezil or addition or substitution of memantine.

SO: Evidence-based medicine

YR: 2013

VL: 18

NO: 2

PG: 62-3

XR: EMBASE 2013193089

PT: Journal: Note

KY: add on therapy // *Alzheimer disease/dt [Drug Therapy] // behavior // clinical decision making // clinical protocol // cognition // controlled study // daily life activity // double blind procedure // drug substitution // drug withdrawal // follow up // human // intention to treat analysis // major clinical study // multicenter study // note // outcome assessment // randomized controlled trial // sample size // *donepezil/ct [Clinical Trial] // *donepezil/cb [Drug Combination] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy] // *memantine/ct [Clinical Trial] // *memantine/cb [Drug Combination] // *memantine/do [Drug Dose] // *memantine/dt [Drug Therapy] // placebo

DOI: 10.1136/eb-2012-100722

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/503/CN-00908503/frame.html>

Record #35 of 370



ID: CN-00871905

AU: Pa J

AU: Berry AS

AU: Compagnone M

AU: Boccanfuso J

AU: Greenhouse I

AU: Rubens MT

AU: Johnson JK

AU: Gazzaley A

TI: Cholinergic enhancement of functional networks in older adults with mild cognitive impairment.

SO: Annals of neurology

YR: 2013

VL: 73

NO: 6

PG: 762-73

PM: PUBMED 23447373

XR: EMBASE 2013494806

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Brain [drug effects] [physiopathology];Cholinesterase Inhibitors [therapeutic use];Double-Blind Method;Indans [therapeutic use];Longitudinal Studies;Mild Cognitive Impairment [drug therapy] [physiopathology] [psychology];Nerve Net [drug effects] [physiology];Photic Stimulation [methods];Piperidines [therapeutic use];Reaction Time [drug effects] [physiology];Up-Regulation [drug effects] [physiology];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]


CC: SR-DEMENTIA

DOI: 10.1002/ana.23874

AB: OBJECTIVE: The importance of the cholinergic system for cognitive function has been well documented in animal and human studies. The objective of this study was to elucidate the cognitive and functional connectivity changes associated with enhanced acetylcholine levels. We hypothesized that older adults with mild memory deficits would show behavioral and functional network enhancements with an acetylcholinesterase inhibitor treatment (donepezil) when compared to a placebo control group. METHODS: We conducted a 3-month, double-blind, placebo-controlled study on the effects of donepezil in 27 older adults with mild memory deficits. Participants completed a delayed recognition memory task. Functional magnetic resonance imaging (fMRI) scans were collected at baseline prior to treatment and at 3-month follow-up while subjects were on a 10mg daily dose of donepezil or placebo. RESULTS: Donepezil treatment significantly enhanced the response time for face and scene memory probes when compared to the placebo group. A group-by-visit interaction was identified for the functional network connectivity of the left fusiform face area (FFA) with the hippocampus and inferior frontal junction, such that the treatment group showed increased connectivity over time when compared to the placebo group. Additionally, the enhanced functional network connectivity of the FFA and hippocampus significantly predicted memory response time at 3-month follow-up in the treatment group. INTERPRETATION: These findings suggest that increased cholinergic transmission improves goal-directed neural processing and cognitive ability and may serve to facilitate communication across functionally-connected attention and memory networks. Longitudinal fMRI is a useful method for elucidating the

neural changes associated with pharmacological modulation and is a potential tool for monitoring intervention efficacy in clinical trials.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/905/CN-00871905/frame.html>

Record #36 of 370 

ID: CN-00872145

AU: NCT01849042


TI: A multicenter, randomized, open-label, prospective study to estimate the add-on effects of memantine as Ebixa oral pump on language in moderate to severe Alzheimer's disease patients already receiving donepezil

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2013

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/145/CN-00872145/frame.html>

Record #37 of 370 

ID: CN-00872167

AU: NCT01955161


TI: Randomised, double-blind, parallel-group, placebo-controlled, fixed-dose study of Lu AE58054 in patients with mild - moderate Alzheimer's disease treated with donepezil

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2013

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/167/CN-00872167/frame.html>

Record #38 of 370 

ID: CN-00872968

AU: Hashimoto Kenji

TI: Potential role of the sigma-1 receptor chaperone in the beneficial effects of donepezil in dementia with Lewy bodies

SO: Clinical psychopharmacology & neuroscience

YR: 2013


VL: 11

NO: 1

PG: 43-4

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/968/CN-00872968/frame.html>

Record #39 of 370 

ID: CN-00872153

AU: NCT01822951

TI: Comparison of cerebrolysin and donepezil: a randomized, double-blind, controlled trial on efficacy and safety in patients with mild to moderate Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2013

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/153/CN-00872153/frame.html>

Record #40 of 370

ID: CN-00872165

AU: NCT01852110

TI: A seamless phase IIa/IIb, multicenter, randomized, double-blind, placebo-controlled, parallel group trial to evaluate the efficacy and safety of MK-7622 as an adjunctive therapy to donepezil for symptomatic treatment in subjects with Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2013

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/165/CN-00872165/frame.html>

Record #41 of 370



ID: CN-00863216

AU: Cummings Jeffrey L

AU: Geldmacher David

AU: Farlow Martin

AU: Sabbagh Marwan

AU: Christensen Daniel

AU: Betz Peter

TI: High-Dose Donepezil (23 mg/day) for the Treatment of Moderate and Severe Alzheimer's Disease: Drug Profile and Clinical Guidelines

SO: CNS neuroscience & therapeutics

YR: 2013

VL: 19

NO: 5

PG: 294-301

XR: EMBASE 2013271739

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/216/CN-00863216/frame.html>

Record #42 of 370



ID: CN-00883324

AU: Molho E

AU: Barba A

AU: Feustel P

AU: Higgins D

AU: Factor S

TI: Double-blind, placebo-controlled trial of donepezil for dementia or mild cognitive impairment in Parkinson disease

SO: Journal of Parkinson's Disease

YR: 2013

VL: Conference: 3rd World Parkinson Congress Montreal, QC Canada. Conference Start: 20131001 Conference End: 20131004. Conference Publication:

NO: var.pagings

PG: 106

XR: EMBASE 71248662

CC: SR-DEMENTIA

DOI: 10.3233/JPD-139905

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/324/CN-00883324/frame.html>

Record #43 of 370



ID: CN-00905699

AU: Doyle OM

AU: Ashburner J

AU: Zelaya FO

AU: Williams SCR

AU: Mehta MA

AU: Marquand AF

TI: Multivariate decoding of brain images using ordinal regression.

SO: NeuroImage

YR: 2013

VL: 81

PG: 347-57

XR: EMBASE 2013372028

PT: Journal: Article

KY: accuracy // adult // analytical error // article // brain blood flow // *brain radiography // classification // controlled study // crossover procedure // double blind procedure // electroencephalogram // human // human experiment // intermethod comparison // male // *multivariate analysis // *neuroimaging // neuromodulation // normal human // nuclear magnetic resonance imaging // nuclear magnetic resonance scanner // *ordinal regression // *pharmacological neuroimaging // priority journal // probability // randomized controlled trial // *regression analysis // statistical model // volunteer // donepezil/ct [Clinical Trial] // donepezil/po [Oral Drug Administration] // ketamine/ct [Clinical Trial] // lamotrigine/ct [Clinical Trial] // placebo // risperidone/ct [Clinical Trial] // scopolamine/ct [Clinical Trial] // scopolamine/sc [Subcutaneous Drug Administration]

DOI: 10.1016/j.neuroimage.2013.05.036

AB: Neuroimaging data are increasingly being used to predict potential outcomes or groupings, such as clinical severity, drug dose response, and transitional illness states. In these examples, the variable (target) we want to predict is ordinal in nature. Conventional classification schemes assume that the targets are nominal and hence ignore their ranked nature, whereas parametric and/or non-parametric regression models enforce a metric notion of distance between classes. Here, we propose a novel, alternative multivariate approach that overcomes these limitations - whole brain probabilistic ordinal regression using a Gaussian process framework. We applied this technique to two data sets of pharmacological neuroimaging data from healthy volunteers. The first study was designed to investigate the effect of ketamine on brain activity and its subsequent modulation with two compounds - lamotrigine and risperidone. The second study investigates the effect of scopolamine on cerebral blood flow and its modulation using donepezil. We compared ordinal regression to multi-class classification schemes and metric regression. Considering the modulation of ketamine with

lamotrigine, we found that ordinal regression significantly outperformed multi-class classification and metric regression in terms of accuracy and mean absolute error. However, for risperidone ordinal regression significantly outperformed metric regression but performed similarly to multi-class classification both in terms of accuracy and mean absolute error. For the scopolamine data set, ordinal regression was found to outperform both multi-class and metric regression techniques considering the regional cerebral blood flow in the anterior cingulate cortex. Ordinal regression was thus the only method that performed well in all cases. Our results indicate the potential of an ordinal regression approach for neuroimaging data while providing a fully probabilistic framework with elegant approaches for model selection. 2013.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/699/CN-00905699/frame.html>

Record #44 of 370



ID: CN-00907833

AU: Lopez-del-Hoyo Y

AU: Olivan B

AU: Luciano JV

AU: Mayoral F

AU: Roca M

AU: Gili M

AU: Andres E

AU: Serrano-Blanco A

AU: Collazo F

AU: Araya R

AU: Banos R

AU: Botella C

AU: Magallon R

AU: Garcia-Campayo J

TI: Low intensity vs. self-guided Internet-delivered psychotherapy for major depression: A multicenter, controlled, randomized study.

SO: BMC psychiatry

YR: 2013

VL: 13

XR: EMBASE 2013253193

PT: Journal: Article

KY: adult // aged // article // Beck Depression Inventory // Client Service Receipt Inventory // controlled study // disease severity // female // health care delivery // health service // human // *low intensity delivered psychotherapy // major clinical study // *major depression/dm [Disease Management] // *major depression/th [Therapy] // male // multicenter study // primary medical care // psychologic test // *psychotherapy // quality of life // randomized controlled trial // *self guided internet delivered psychotherapy // social work // Spain

CC: SR-DEPRESSN

DOI: 10.1186/1471-244X-13-21

AB: Background: Major depression will become the second most important cause of disability in 2020. Computerized cognitive-behaviour therapy could be an efficacious and cost-effective option for its treatment. No studies on cost-effectiveness of low intensity vs self-guided psychotherapy has been carried out. The aim of this study is to assess the efficacy of low intensity vs self-guided psychotherapy for major depression in the Spanish health system. Methods: The study is made up of 3 phases: 1.- Development of a computerized cognitive-behaviour therapy for depression tailored to Spanish health system. 2.- Multicenter controlled, randomized study: A sample (N=450 patients) with mild/moderate depression recruited in primary care. They should have internet availability at home, not receive any previous psychological treatment, and not suffer from any other severe somatic or psychological disorder. They will be allocated to one of 3 treatments: a) Low intensity Internet-delivered psychotherapy + improved treatment as usual (ITAU) by GP, b) Self-guided Internet-delivered psychotherapy + ITAU or c) ITAU. Patients will be diagnosed with MINI psychiatric interview. Main outcome variable will be Beck Depression Inventory. It will be also administered EuroQoL 5D (quality of life) and Client Service Receipt Inventory (consume of health and social services). Patients will be assessed at baseline, 3 and 12 months. An intention to treat and a per protocol analysis will be performed. Discussion: The comparisons between low intensity and self-guided are infrequent, and also a comparative economic evaluation between them and compared with usual treatment in primary. The strength of the study is that it is a multicenter, randomized, controlled trial of low intensity and self-guided Internet-delivered psychotherapy for depression in primary care, being the treatment completely integrated in primary care setting. Trial registration: Clinical Trials NCT01611818. 2013 Lopez-del-Hoyo et al.; licensee BioMed Central Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/833/CN-00907833/frame.html>

Record #45 of 370



ID: CN-00915562

AU: Parish SL

AU: Swaine JG

AU: Son E

AU: Luken K

TI: Determinants of cervical cancer screening among women with intellectual disabilities:
Evidence from medical records.

SO: Public health reports

YR: 2013

VL: 128

NO: 6

PG: 519-26

XR: EMBASE 2013709270


PT: Journal: Article

KY: adult // aged // article // *cancer screening // controlled study // demography // female // gynecologist // health care personnel // human // *intellectual impairment // major clinical study // medical record review // multicenter study // obstetrician // Papanicolaou test // priority journal // randomized controlled trial // residential home // rural population // United States // *uterine cervix cancer

AB: Objective. We examined receipt of cervical cancer screening and determinants of screening for women with intellectual disabilities in one Southeastern state. Methods. Using medical records data from 2006 through 2010 for community-dwelling women with intellectual disabilities who were 18-65 years of age (n5163), we employed descriptive and bivariate statistics and a multivariate regression model to examine receipt of cervical cancer screening and the determinants of cervical cancer screening across women's sociodemographic and health-care provider characteristics. Results. Of women 18-65 years of age with intellectual disabilities, 55% received a Papanicolaou (Pap) test during 2008-2010, markedly below the Healthy People 2020 targets or rates of Pap test receipt of women without intellectual disabilities. Women with intellectual disabilities who lived in residential facilities, those who lived in rural communities, and those who had an obstetrician/gynecologist had higher rates of receipt of care than other women with intellectual disabilities. Conclusions.

Assertive measures are required to improve the receipt of cervical cancer screening among women with intellectual disabilities. Such measures could include education of women with intellectual disabilities, as well as their paid and family caregivers, and incentives for health-care providers who achieve screening targets. 2013 Association of Schools and Programs of Public Health.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/562/CN-00915562/frame.html>

Record #46 of 370 

ID: CN-00920190

AU: Chew EY

AU: SanGiovanni JP

AU: Ferris FL

AU: Wong WT

AU: Agron E

AU: Clemons TE

AU: Sperduto R

AU: Danis R

AU: Chandra SR

AU: Blodi BA

AU: Domalpally A

AU: Elman MJ

AU: Antoszyk AN

AU: Ruby AJ

AU: Orth D

AU: Bressler SB

AU: Fish GE

AU: Hubbard GB

AU: Klein ML

AU: Friberg TR

AU: Rosenfeld PJ

AU: Toth CA

AU: Bernstein P

TI: Lutein/zeaxanthin for the treatment of age-related cataract: AREDS2 randomized trial report no. 4.

SO: JAMA Ophthalmology

YR: 2013

VL: 131

NO: 7

PG: 843-50

XR: EMBASE 2013448529

PT: Journal: Article

KY: adult // aged // aphakia // article // cataract extraction // controlled study // double blind procedure // female // follow up // human // major clinical study // male // multicenter study // priority journal // pseudophakia // randomized controlled trial // retina macula age related degeneration // risk factor // *senile cataract/dt [Drug Therapy] // *senile cataract/su [Surgery] // docosahexaenoic acid // icosapentaenoic acid // placebo // *xanthophyll/ct [Clinical Trial] // *xanthophyll/cb [Drug Combination] // *xanthophyll/dt [Drug Therapy] // *zeaxanthin/ct [Clinical Trial] // *zeaxanthin/cb [Drug Combination] // *zeaxanthin/dt [Drug Therapy]

DOI: 10.1001/jamaophthalmol.2013.4412

AB: Importance Age-related cataract is a leading cause of visual impairment in the United States. The prevalence of age-related cataract is increasing, with an estimated 30.1 million Americans likely to be affected by 2020. OBJECTIVE To determine whether daily oral supplementation with lutein/zeaxanthin affects the risk for cataract surgery. DESIGN, SETTING, AND PATIENTS The Age-Related Eye Disease Study 2 (AREDS2), a multicenter, double-masked clinical trial, enrolled 4203 participants, aged 50 to 85 years, at risk for progression to advanced age-related macular degeneration. INTERVENTIONS Participants were randomly assigned to daily placebo; lutein/zeaxanthin, 10mg/2mg; omega-3 long-chain polyunsaturated fatty acids, 1 g; or a combination to evaluate the effects on the primary outcome of progression to advanced age-related macular degeneration. MAIN OUTCOMES AND MEASURES Cataract surgery was documented at annual study examination with the presence of pseudophakia or aphakia, or reported during telephone calls at 6-month intervals between

study visits. Annual best-corrected visual acuity testing was performed. A secondary outcome of AREDS2 was to evaluate the effects of lutein/zeaxanthin on the subsequent need for cataract surgery. RESULTS A total of 3159 AREDS2 participants were phakic in at least 1 eye and 1389 of 6027 study eyes underwent cataract surgery during the study, with median follow-up of 4.7 years. The 5-year probability of progression to cataract surgery in the no lutein/zeaxanthin group was 24%. For lutein/zeaxanthin vs no lutein/zeaxanthin, the hazard ratios for progression to cataract surgery was 0.96 (95%CI, 0.84-1.10; P = .54). For participants in the lowest quintile of dietary intake of lutein/zeaxanthin, the hazard ratio comparing lutein/zeaxanthin vs no lutein/zeaxanthin for progression to cataract surgery was 0.68 (95%CI, 0.48-0.96; P = .03). The hazard ratio for 3 or more lines of vision loss was 1.03 (95%CI, 0.93-1.13; P = .61 for lutein/zeaxanthin vs no lutein/zeaxanthin). CONCLUSIONS AND RELEVANCE Daily supplementation with lutein/zeaxanthin had no statistically significant overall effect on rates of cataract surgery or vision loss.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/190/CN-00920190/frame.html>

Record #47 of 370



ID: CN-00876616

AU: Chew EY

AU: SanGiovanni JP

AU: Ferris FL

AU: Wong WT

AU: Agron E

AU: Clemons TE

AU: Sperduto R

AU: Danis R

AU: Chandra SR

AU: Blodi BA

AU: Domalpally A

AU: Elman MJ

AU: Antoszyk AN

AU: Ruby AJ

AU: Orth D

AU: Bressler SB

AU: Fish GE

AU: Hubbard GB

AU: Klein ML

AU: Friberg TR

AU: Rosenfeld PJ

AU: Toth CA

AU: Bernstein P

TI: Lutein/zeaxanthin for the treatment of age-related cataract: AREDS2 randomized trial report no. 4.

SO: JAMA ophthalmology

YR: 2013

VL: 131

NO: 7

PG: 843-50

PM: PUBMED 23645227

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, N.I.H., Intramural

KY: Administration, Oral;Aging;Cataract [diagnosis] [drug therapy] [physiopathology];Cataract Extraction [statistics & numerical data];Dietary Supplements;Disease Progression;Double-Blind Method;Drug Therapy, Combination;Fatty Acids, Omega-3 [therapeutic use];Lutein [blood] [therapeutic use];Vision Disorders [diagnosis];Visual Acuity;Xanthophylls [blood] [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1001/jamaophthalmol.2013.4412

AB: IMPORTANCE: Age-related cataract is a leading cause of visual impairment in the United States. The prevalence of age-related cataract is increasing, with an estimated 30.1 million Americans likely to be affected by 2020. OBJECTIVE: To determine whether daily oral supplementation with lutein/zeaxanthin affects the risk for cataract surgery. DESIGN, SETTING, AND PATIENTS: The Age-Related Eye Disease Study 2 (AREDS2), a multicenter, double-masked clinical trial, enrolled 4203 participants, aged 50 to 85 years, at risk for progression to advanced age-related macular degeneration. INTERVENTIONS: Participants were randomly

assigned to daily placebo; lutein/zeaxanthin, 10mg/2mg; omega-3 long-chain polyunsaturated fatty acids, 1 g; or a combination to evaluate the effects on the primary outcome of progression to advanced age-related macular degeneration. MAIN OUTCOMES AND MEASURES: Cataract surgery was documented at annual study examination with the presence of pseudophakia or aphakia, or reported during telephone calls at 6-month intervals between study visits. Annual best-corrected visual acuity testing was performed. A secondary outcome of AREDS2 was to evaluate the effects of lutein/zeaxanthin on the subsequent need for cataract surgery. RESULTS: A total of 3159 AREDS2 participants were phakic in at least 1 eye and 1389 of 6027 study eyes underwent cataract surgery during the study, with median follow-up of 4.7 years. The 5-year probability of progression to cataract surgery in the no lutein/zeaxanthin group was 24%. For lutein/zeaxanthin vs no lutein/zeaxanthin, the hazard ratios for progression to cataract surgery was 0.96 (95% CI, 0.84-1.10; P = .54). For participants in the lowest quintile of dietary intake of lutein/zeaxanthin, the hazard ratio comparing lutein/zeaxanthin vs no lutein/zeaxanthin for progression to cataract surgery was 0.68 (95% CI, 0.48-0.96; P = .03). The hazard ratio for 3 or more lines of vision loss was 1.03 (95% CI, 0.93-1.13; P = .61 for lutein/zeaxanthin vs no lutein/zeaxanthin). CONCLUSIONS AND RELEVANCE: Daily supplementation with lutein/zeaxanthin had no statistically significant overall effect on rates of cataract surgery or vision loss. TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00345176.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/616/CN-00876616/frame.html>

Record #48 of 370



ID: CN-00862011

AU: Deneux-Tharaux C

AU: Sentilhes L

AU: Maillard F

AU: Closset E

AU: Vardon D

AU: Lepercq J

AU: Goffinet F

TI: Effect of routine controlled cord traction as part of the active management of the third stage of labour on postpartum haemorrhage: multicentre randomised controlled trial (TRACOR).

SO: BMJ (Clinical research ed.)

YR: 2013

VL: 346

PG: f1541


PM: PUBMED 23538918

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adolescent;France;Labor Stage, Third;Labor, Obstetric;Placenta;Postpartum Hemorrhage [prevention & control];Treatment Outcome;Umbilical Cord;Adult[checkword];Female[checkword];Humans[checkword];Pregnancy[checkword];Young Adult[checkword]

AB: OBJECTIVE: To assess the impact of controlled cord traction on the incidence of postpartum haemorrhage and other characteristics of the third stage of labour in a high resource setting. DESIGN: Randomised controlled trial. SETTING: Five university hospital maternity units in France. PARTICIPANTS: Women aged 18 or more with a singleton fetus at 35 or more weeks' gestation and planned vaginal delivery. INTERVENTIONS: Women were randomly assigned to management of the third stage of labour by controlled cord traction or standard placenta expulsion (awaiting spontaneous placental separation before facilitating expulsion). Women in both arms received prophylactic oxytocin just after birth. MAIN OUTCOME MEASURE: Incidence of postpartum haemorrhage \geq 500 mL as measured in a collector bag. RESULTS: The incidence of postpartum haemorrhage did not differ between the controlled cord traction arm (9.8%, 196/2005) and standard placenta expulsion arm (10.3%, 206/2008): relative risk 0.95 (95% confidence interval 0.79 to 1.15). The need for manual removal of the placenta was significantly less frequent in the controlled cord traction arm (4.2%, 85/2033) compared with the standard placenta expulsion arm (6.1%, 123/2024): relative risk 0.69, 0.53 to 0.90; as was third stage of labour of more than 15 minutes (4.5%, 91/2030 and 14.3%, 289/2020, respectively): relative risk 0.31, 0.25 to 0.39. Women in the controlled cord traction arm reported a significantly lower intensity of pain and discomfort during the third stage than those in the standard placenta expulsion arm. No uterine inversion occurred in either arm. CONCLUSIONS: In a high resource setting, the use of controlled cord traction for the management of placenta expulsion had no significant effect on the incidence of postpartum haemorrhage and other markers of postpartum blood loss. Evidence to recommend routine controlled cord traction for the management of placenta expulsion to prevent postpartum haemorrhage is therefore lacking. TRIAL REGISTRATION: ClinicalTrials.gov NCT01044082.

US: <http://onlinelibrary.wiley.com/doi/10.1002/1469758011000862>

Record #49 of 370 

ID: CN-00966010

AU: López-del-Hoyo Y

AU: Olivan B

AU: Luciano JV

AU: Mayoral F

AU: Roca M

AU: Gili M

AU: Andres E

AU: Serrano-Blanco A

AU: Collazo F

AU: Araya R

AU: Baños R

AU: Botella C

AU: Magallón R

AU: García-Campayo J

TI: Low intensity vs. self-guided internet-delivered psychotherapy for major depression: a multicenter, controlled, randomized study.

SO: BMC psychiatry

YR: 2013

VL: 13

PG: 21

PM: PUBMED 23312003

PT: Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Clinical Protocols;Cognitive Therapy [economics] [methods];Cost-Benefit Analysis;Depressive Disorder, Major [economics] [psychology] [therapy];Internet [economics];Research Design;Therapy, Computer-Assisted [methods];Treatment Outcome;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

AB: BACKGROUND: Major depression will become the second most important cause of disability in 2020. Computerized cognitive-behaviour therapy could be an efficacious and cost-effective option for its treatment. No studies on cost-effectiveness of low intensity vs self-guided psychotherapy has been carried out. The aim of this study is to assess the efficacy of low intensity vs self-guided psychotherapy for major depression in the Spanish health system. **METHODS:** The study is made up of 3 phases: 1.- Development of a computerized cognitive-behaviour therapy for depression tailored to Spanish health system. 2.- Multicenter controlled, randomized study: A sample (N=450 patients) with mild/moderate depression recruited in primary care. They should have internet availability at home, not receive any previous psychological treatment, and not suffer from any other severe somatic or psychological disorder. They will be allocated to one of 3 treatments: a) Low intensity Internet-delivered psychotherapy + improved treatment as usual (ITAU) by GP, b) Self-guided Internet-delivered psychotherapy + ITAU or c) ITAU. Patients will be diagnosed with MINI psychiatric interview. Main outcome variable will be Beck Depression Inventory. It will be also administered EuroQol 5D (quality of life) and Client Service Receipt Inventory (consume of health and social services). Patients will be assessed at baseline, 3 and 12 months. An intention to treat and a per protocol analysis will be performed. **DISCUSSION:** The comparisons between low intensity and self-guided are infrequent, and also a comparative economic evaluation between them and compared with usual treatment in primary. The strength of the study is that it is a multicenter, randomized, controlled trial of low intensity and self-guided Internet-delivered psychotherapy for depression in primary care, being the treatment completely integrated in primary care setting. **TRIAL REGISTRATION:** Clinical Trials NCT01611818.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/010/CN-00966010/frame.html>

Record #50 of 370



ID: CN-00911457

AU: Liu H

AU: Yang H-L

AU: Xu J-W

AU: Wang J-Z

AU: Nie R-H

AU: Li C-F

TI: Artemisinin-naphthoquine combination versus chloroquine-primaquine to treat vivax malaria: An open-label randomized and non-inferiority trial in Yunnan Province, China.

SO: Malaria journal

YR: 2013

VL: 12

NO: 1

XR: EMBASE 2013750091

PT: Journal: Article

KY: abdominal pain/si [Side Effect] // adolescent // anorexia/si [Side Effect] // article // child // China // controlled study // diarrhea/si [Side Effect] // dizziness/si [Side Effect] // drug efficacy // drug safety // female // follow up // headache/si [Side Effect] // heart palpitation/si [Side Effect] // hemoglobinuria/si [Side Effect] // hemolysis/si [Side Effect] // human // major clinical study // male // nausea/si [Side Effect] // open study // *Plasmodium vivax malaria/dt [Drug Therapy] // preschool child // randomized controlled trial // recurrent disease // school child // treatment duration // vomiting/si [Side Effect] // *artemisinin/ae [Adverse Drug Reaction] // *artemisinin/cb [Drug Combination] // *artemisinin/dt [Drug Therapy] // *artemisinin/pd [Pharmacology] // *chloroquine/ae [Adverse Drug Reaction] // *chloroquine/cb [Drug Combination] // *chloroquine/dt [Drug Therapy] // *chloroquine/pd [Pharmacology] // *naphthoquine/ae [Adverse Drug Reaction] // *naphthoquine/cb [Drug Combination] // *naphthoquine/dt [Drug Therapy] // *naphthoquine/pd [Pharmacology] // *primaquine/ae [Adverse Drug Reaction] // *primaquine/cb [Drug Combination] // *primaquine/dt [Drug Therapy] // *primaquine/pd [Pharmacology] // *quinine sulfate/ae [Adverse Drug Reaction] // *quinine sulfate/dt [Drug Therapy] // *quinine sulfate/pd [Pharmacology] // unclassified drug

DOI: 10.1186/1475-2875-12-409

AB: Background: *Plasmodium vivax* is the main malaria parasite in China, and China is now making efforts to eliminate malaria by 2020. Radical cure of *vivax* malaria is one of challenges for malaria elimination. The purpose is to evaluate the efficacy and safety of artemisinin-naphthoquine (ANQ) versus chloroquine-primaquine (CQ-PQ) in treatment of *vivax* malaria in Yunnan Province, China. Methods. An open-label randomized and non-inferiority design, eligible patients with mono-infections of *P. vivax* were randomly assigned to receive either a total target dose of ANQ 24.5 mg/kg (naphthoquine 7 mg/kg and artemisinin 17.5 mg/kg), once a day for three days, or a total CQ dose of 24 mg base/kg, once a day for three days plus a PQ dose of 0.45 mg base/kg/day, once a day for eight days. Patients were followed up for one year. The difference in efficacy between ANQ and CQ-PQ was compared via Wilson's test. Results: By day 42, the number of patients free of recurrence was 125 (98.4%; 95% Confidence interval, 94.4-99.8%) for ANQ arm and 123 (96.1%; 95%CI, 91.1-98.7%) for CQ-PQ, and non-significant ($P = 0.4496$). By day 365, the number was 101 (79.5%; 95%CI, 71.8-85.9%) for ANQ and 106 (82.8%; 95%CI, 75.1-88.9%) for CQ-PQ, and non-significant ($P = 0.610$). So the proportions of patients free of recurrence had no significant difference between ANQ and CQ-PQ groups by day 28, 42 and 365; compared with CQ-PQ, the side effect of ANQ was mild. Conclusion: ANQ is non-inferior to CQ-PQ in terms of patients free of recurrence, and safer than CQ-PQ. 2013 Liu et al.; licensee BioMed Central Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/457/CN-00911457/frame.html>

Record #51 of 370



ID: CN-00875204

AU: Campbell NL

AU: Dexter P

AU: Perkins AJ

AU: Gao S

AU: Li L

AU: Skaar TC

AU: Frame A

AU: Hendrie HC

AU: Callahan CM

AU: Boustani MA

TI: Medication adherence and tolerability of Alzheimer's disease medications: study protocol for a randomized controlled trial.

SO: Trials

YR: 2013

VL: 14

PG: 125

PM: PUBMED 23782591

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, U.S. Gov't, P.H.S.

KY: Alzheimer Disease [diagnosis] [drug therapy] [enzymology] [genetics] [psychology];Brain [drug effects] [enzymology];Cholinesterase Inhibitors [adverse effects] [pharmacokinetics] [therapeutic use];Clinical Protocols;Comorbidity;Drug Interactions;Indiana;Medication Adherence;Memory [drug effects];Neuropsychological Tests;Nootropic Agents [adverse effects] [pharmacokinetics] [therapeutic use];Pharmacogenetics;Polypharmacy;Prospective Studies;Research Design;Risk Factors;Time Factors;Treatment


Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1186/1745-6215-14-125

AB: BACKGROUND: The class of acetylcholinesterase inhibitors (ChEI), including donepezil, rivastigmine, and galantamine, have similar efficacy profiles in patients with mild to moderate Alzheimer's disease (AD). However, few studies have evaluated adherence to these agents. We sought to prospectively capture the rates and reasons for nonadherence to ChEI and determine factors influencing tolerability and adherence. METHODS/DESIGN: We designed a pragmatic randomized clinical trial to evaluate the adherence to ChEIs among older adults with AD. Participants include AD patients receiving care within memory care practices in the greater Indianapolis area. Participants will be followed at 6-week intervals up to 18 weeks to measure the primary outcome of ChEI discontinuation and adherence rates and secondary outcomes of behavioral and psychological symptoms of dementia. The primary outcome will be assessed through two methods, a telephone interview of an informal caregiver and electronic medical record data captured from each healthcare system through a regional health information exchange. The secondary outcome will be measured by the Healthy Aging Brain Care Monitor and the Neuropsychiatric Inventory. In addition, the trial will conduct an exploratory evaluation of the pharmacogenomic signatures for the efficacy and the adverse effect responses to ChEIs. We hypothesized that patient-specific factors, including pharmacogenomics and pharmacokinetic characteristics, may influence the study outcomes. DISCUSSION: This pragmatic trial will engage a diverse population from multiple memory care practices to evaluate the adherence to and tolerability of ChEIs in a real world setting. Engaging participants from multiple healthcare systems connected through a health information exchange will capture valuable clinical and non-clinical influences on the patterns of utilization and tolerability of a class of medications with a high rate of discontinuation. TRIAL REGISTRATION: Clinicaltrials.gov: NCT01362686.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/204/CN-00875204/frame.html>

Record #52 of 370 

ID: CN-00907292

AU: Mahfouz RA

AU: Charafeddine KM

AU: Tanios RF

AU: Karaky NM

AU: Abdul Khalik RN

AU: Daher RT

TI: Apolipoprotein E gene polymorphisms in Lebanese with hypercholesterolemia.

SO: Gene

YR: 2013

VL: 522

NO: 1

PG: 84-8

XR: EMBASE 2013281381

PT: Journal: Article

KY: adult // aged // article // blood sampling // clinical article // clinical assessment // controlled study // *DNA polymorphism // female // gene frequency // genotype // human // *hypercholesterolemia // Lebanon // lipid analysis // male // priority journal // prospective study // randomized controlled trial // apolipoprotein B/ec [Endogenous Compound] // *apolipoprotein E/ec [Endogenous Compound]

DOI: 10.1016/j.gene.2013.03.019

AB: Apolipoprotein E (ApoE) has an important role in the metabolism of lipids through its major isoforms (2, 3, 4). In particular, ApoE 4, has been considered as a major genetic risk factor for cardiovascular diseases (CVD). The aim of our study is to investigate the frequency of ApoE gene polymorphisms (rs 429358C > T, rs 7412C > T) and their relationship to lipid parameters in a group of Lebanese hypercholesterolemic subjects (22 males and 24 females, aged 25-80. years). Lipid profile, apolipoproteins A-I and B were determined using fasting serum samples; and molecular analysis of ApoE polymorphisms using blood in EDTA tubes. The distribution of the four ApoE genotypes detected in this study was: 3/3 (73.9%), 3/4 (17.4%), 2/3 (6.5%), and 2/4 (2.2%) resulting in allelic frequencies for 2, 3 and 4 of 4.3%, 85.9% and 9.8%, respectively. No association was determined among any of the lipid parameters, gender and ApoE genotypes. Lipid parameters were not statistically different among various ApoE genotypes ($p > 0.05$). ApoE 2 frequency was found to be lower than that previously reported for healthy Lebanese (7.2%). CVD is one of the major leading causes of mortality in Lebanon with a reported prevalence of 12.2% in males and 7.7% in females, which incidentally agrees with our finding regarding 4 allelic frequency of 13.6% in males and 6.3% in females. Consequently, larger prospective studies are recommended to highlight the correlation of ApoE polymorphisms to other biochemical and environmental factors involved in CVD. 2013 Elsevier B.V.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/292/CN-00907292/frame.html>

Record #53 of 370



ID: CN-00914375

AU: Grasing K

AU: Mathur D

AU: Newton TF

AU: DeSouza C

TI: Individual predictors of the subjective effects of intravenous cocaine.

SO: Psychiatry research

YR: 2013

VL: 208

NO: 3

PG: 245-51

XR: EMBASE 2013469704

PT: Journal: Article


KY: Addiction Severity Index // adult // article // *cocaine dependence/dt [Drug Therapy] // controlled clinical trial // controlled study // disease association // disease severity // double blind procedure // drug abuse pattern // euphoria // family conflict // human // *intravenous drug abuse // male // marriage // predictive value // priority journal // reinforcement // reward // self report // single blind procedure // social disability // social interaction // social status // veteran // withdrawal syndrome // *cocaine // donepezil/ct [Clinical Trial] // donepezil/dt [Drug Therapy] // donepezil/iv [Intravenous Drug Administration] // placebo

DOI: 10.1016/j.psychres.2013.05.028

AB: The subjective and reinforcing effects of addictive substances can vary greatly between individuals. This study compared the relative contributions of baseline drug use, craving, stressful life events, and social factors in determining the subjective effects of cocaine in individual participants. Twelve veterans meeting criteria for cocaine dependence were evaluated in a laboratory setting. Self-report of the subjective effects of intravenous cocaine was recorded following single- and double-blind, placebo-controlled injections. Increased positive subjective effects of cocaine, including drug-induced 'good' effects and the value of intravenous injections, were most strongly correlated with greater family and social dysfunction measured through the Addiction Severity Index (ASI). Social dysfunction was the

strongest predictor of cocaine-induced euphoria, accounting for approximately one-half of its variability. Participants who were dissatisfied with their current marital status reported almost no 'bad' effects of cocaine but instead reported increased drug-induced 'high', euphoria, and injection value. Although further research is required to determine the generalizability of this association, our findings are parallel to recent preclinical results showing that social interaction can attenuate psychostimulant reward. Effects of substance abuse treatment that rely on improved social function may be mediated through changes in the brain's reinforcement system that modify the rewarding effects of cocaine. 2013.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/375/CN-00914375/frame.html>

Record #54 of 370 

ID: CN-00876948

AU: Annane D

AU: Timsit JF

AU: Megarbane B

AU: Martin C

AU: Misset B

AU: Mourvillier B

AU: Siami S

AU: Chagnon JL

AU: Constantin JM

AU: Petitpas F

AU: Souweine B

AU: Amathieu R

AU: Forceville X

AU: Charpentier C

AU: Tesnière A

AU: Chastre J

AU: Bohe J

AU: Colin G

AU: Cariou A

AU: Renault A

AU: Brun-Buisson C

AU: Bellissant E

TI: Recombinant human activated protein C for adults with septic shock: a randomized controlled trial.

SO: American journal of respiratory and critical care medicine

YR: 2013

VL: 187

NO: 10

PG: 1091-7

PM: PUBMED 23525934

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Anti-Infective Agents [therapeutic use];Anti-Inflammatory Agents [therapeutic use];Double-Blind Method;Drug Therapy, Combination [methods];Fludrocortisone [therapeutic use];Hydrocortisone [therapeutic use];Protein C [therapeutic use];Recombinant Proteins [therapeutic use];Safety-Based Drug Withdrawals;Shock, Septic [drug therapy];Treatment Outcome;Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1164/rccm.201211-2020OC

AB: RATIONALE: A decade after drotrecogin alfa (activated) (DAA) was released on the market worldwide, its benefit-to-risk ratio remains a matter of debate. OBJECTIVES: The current investigator-led trial was designed to evaluate the efficacy and safety of DAA, in combination with low-dose steroids, in adults with persistent septic shock. METHODS: This was a multicenter (24 intensive care units), placebo-controlled, double-blind, 2 × 2 factorial design trial in which adults with persistent septic shock and no contraindication to DAA were randomly assigned to DAA alone (24 µg/kg/h for 96 h), hydrocortisone and fludrocortisone alone, their respective combinations, or their respective placebos. Primary outcome was mortality rate on Day 90. MEASUREMENTS AND MAIN RESULTS: On October 25, 2011, the trial was suspended after the withdrawal from the market of DAA. The Scientific Committee decided to continue the trial according to a two parallel group design comparing low-dose steroids with their placebos and to analyze the effects of DAA on patients included before trial suspension. At the time trial was suspended, 411 patients had been recruited, 208 had received DAA, and 203 had received its placebo. There was no significant interaction between

DAA and low-dose steroids ($P = 0.47$). On Day 90, there were 99 deaths (47.6%) among the 208 patients receiving DAA and 94 deaths (46.3%) among the 203 patients receiving placebo ($P = 0.79$). There was no evidence of a difference between DAA and its placebo for any secondary outcomes or serious adverse events. CONCLUSIONS: In adults with established and severe septic shock, DAA showed no evidence of benefit or harm. Clinical trial registered with www.clinicaltrials.gov (NCT00625209).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/948/CN-00876948/frame.html>

Record #55 of 370 

ID: CN-00839964

AU: Abbas Waseem SM

AU: Hossain M

AU: Aijaz Abbas Rizvi S

AU: Ahmad Z

AU: Islam N

TI: Oxidative stress and lipid profile in COPD patients: Beneficial role of exercise and scope for improvement.

SO: Biomedical Research (India)

YR: 2013

VL: 24

NO: 1

PG: 135-8

XR: EMBASE 2013032922

PT: Journal: Article

KY: adult // article // *chronic obstructive lung disease // clinical article // controlled study // enzyme blood level // *exercise // forced expiratory volume // forced vital capacity // human // lipid analysis // male // *oxidative stress // catalase/ec [Endogenous Compound] // cholesterol/ec [Endogenous Compound] // glutathione peroxidase/ec [Endogenous Compound] // high density lipoprotein/ec [Endogenous Compound] // *lipid/ec [Endogenous Compound] // malonaldehyde/ec [Endogenous Compound] // superoxide dismutase/ec

[Endogenous Compound] // triacylglycerol/ec [Endogenous Compound] // very low density lipoprotein/ec [Endogenous Compound]

CC: SR-AIRWAYS

AB: Smoking is a major risk factor in COPD [Chronic Obstructive Pulmonary Disease]. It contributes to inflammation and oxidative stress which are implicated in hyperlipidemia and lung function decline. Exercise may result in anti-inflammatory effects which limit smoking induced changes in COPD. The aim of the present study was to evaluate the oxidant anti-oxidant imbalance and lipid profile in exercising and non-exercising COPD groups and included 50 patients in each group. The results indicated that the lung functions were significantly reduced in those not doing exercise. The serum levels of antioxidant enzymes (SOD, Catalase and GPX) were significantly lower in non exercising group as compared to exercising group($p<0.001$) while the levels of MDA (Malondialdehyde) were significantly higher in the same group($p<0.001$). The levels of HDL($p<0.001$) were significantly higher and VLDL($p=0.03$) were significantly lower in exercising group as compared to non exercising group. The present study indicates that exercise has beneficial role in COPD and reduces Oxidant Anti Oxidant imbalance and improves lipid profile and it may be due to anti-inflammatory effects of exercise.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/964/CN-00839964/frame.html>

Record #56 of 370



ID: CN-00913999

AU: Reading CL

AU: Stickney DR

AU: Flores-Riveros J

AU: Destiche DA

AU: Ahlem CN

AU: Cefalu WT

AU: Frincke JM

TI: A synthetic anti-inflammatory sterol improves insulin sensitivity in insulin-resistant obese impaired glucose tolerance subjects.

SO: Obesity (Silver Spring, Md.)

YR: 2013

VL: 21

NO: 9

PG: E343-E349

XR: EMBASE 2013616434

PT: Journal: Article

KY: adult // aged // article // body mass // cell stimulation // clinical article // controlled clinical trial // controlled study // cytokine release // double blind procedure // drug efficacy // drug mechanism // drug structure // female // human // human cell // *impaired glucose tolerance/dt [Drug Therapy] // insulin resistance // *insulin sensitivity // male // multicenter study // *obesity // peripheral blood mononuclear cell // randomized controlled trial // treatment outcome // *17 alpha ethynylandrost 5 ene 3 beta, 7 beta, 17 beta triol/an [Drug Analysis] // *17 alpha ethynylandrost 5 ene 3 beta, 7 beta, 17 beta triol/dt [Drug Therapy] // *17 alpha ethynylandrost 5 ene 3 beta, 7 beta, 17 beta triol/pd [Pharmacology] // adiponectin/ec [Endogenous Compound] // C reactive protein/ec [Endogenous Compound] // cytokine/ec [Endogenous Compound] // high density lipoprotein cholesterol/ec [Endogenous Compound] // insulin // lipopolysaccharide // placebo // *sterol/an [Drug Analysis] // *sterol/dt [Drug Therapy] // *sterol/pd [Pharmacology] // triolex // unclassified drug

DOI: 10.1002/oby.20207

AB: Objective To study the activity of HE3286 (17alpha-ethynylandrost-5-ene-3beta,7beta,17beta-triol), an anti-inflammatory sterol that is active in models of obesity-induced inflammation and insulin resistance in high body mass index (BMI) subjects with impaired glucose tolerance (IGT). Design and Methods HE3286 was explored in high BMI IGT subjects using hyperinsulinemic, euglycemic clamp studies. Results In insulin-resistant subjects, HE3286 significantly increased day 29 insulin-stimulated glucose disposal and HDL cholesterol, and decreased C-reactive protein (CRP) compared to placebo. For HE3286, change in M value showed a significant negative correlation with baseline M value. Subjects with baseline M value below the median (4.2 mg/kg/min) had significantly lower adiponectin and higher lipopolysaccharide-stimulated peripheral blood mononuclear cell cytokine secretion. After 28 days of HE3286 treatment, adiponectin levels were significantly increased in insulin-resistant (baseline M < 4.2), but not insulin-sensitive (baseline M > 4.2) subjects, compared to placebo. Conclusions HE3286 significantly increased the frequency of subjects with increased insulin-stimulated glucose disposal and HDL, and decreased CRP compared to placebo, in insulin-resistant, but not insulin-sensitive subjects. Thus, HE3286 may preferentially benefit insulin-resistant, inflamed, high BMI IGT subjects. Copyright 2013 The Obesity Society.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/999/CN-00913999/frame.html>

Record #57 of 370



ID: CN-00911279

AU: Wong KL

AU: Lee KBL

AU: Tai BC

AU: Law P

AU: Lee EH

AU: Hui JHP

TI: Injectable cultured bone marrow-derived mesenchymal stem cells in varus knees with cartilage defects undergoing high tibial osteotomy: A prospective, randomized controlled clinical trial with 2 years' follow-up.

SO: Arthroscopy - Journal of Arthroscopic and Related Surgery

YR: 2013

VL: 29

NO: 12

PG: 2020-8

XR: EMBASE 2013757002

PT: Journal: Article

KY: adult // article // body mass // controlled study // female // follow up // hematopoietic stem cell // *hematopoietic stem cell transplantation // human // human cell // joint mobility // *knee osteoarthritis/dt [Drug Therapy] // *knee osteoarthritis/su [Surgery] // *knee osteoarthritis/th [Therapy] // major clinical study // male // mesenchymal stem cell // *mesenchymal stem cell transplantation // nuclear magnetic resonance imaging // randomized controlled trial // *tibia osteotomy // varus knee // hyaluronic acid/dt [Drug Therapy] // hyaluronic acid/ar [Intraarticular Drug Administration]

DOI: 10.1016/j.arthro.2013.09.074

AB: Purpose To analyze the results of the use of intra-articular cultured autologous bone marrow-derived mesenchymal stem cell (MSC) injections in conjunction with microfracture and medial opening-wedge high tibial osteotomy (HTO). Methods Fifty-six knees in 56 patients with unicompartamental osteoarthritic knees and genu varum were randomly allocated to the cell-recipient group (n = 28) or control group (n = 28). Patients who had a joint line congruity angle of more than 2, malalignment of the knee from femoral causes, a fixed flexion deformity, or age older than 55 years were excluded. All patients underwent HTO and microfracture. The

cell-recipient group received intra-articular injection of cultured MSCs with hyaluronic acid 3 weeks after surgery, whereas the control group only received hyaluronic acid. The primary outcome measure was the International Knee Documentation Committee (IKDC) score at intervals of 6 months, 1 year, and 2 years postoperatively. Secondary outcome measures were Tegner and Lysholm clinical scores and 1-year postoperative Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART) scores. Results The median age of the patients was 51 years, with a mean body mass index of 23.85. Both treatment arms achieved improvements in Tegner, Lysholm, and IKDC scores. After adjustment for age, baseline scores, and time of evaluation, the cell-recipient group showed significantly better scores. The effect of treatment showed an added improvement of 7.65 (95% confidence interval [CI], 3.04 to 12.26; $P = .001$) for IKDC scores, 7.61 (95% CI, 1.44 to 13.79; $P = .016$) for Lysholm scores, and 0.64 (95% CI, 0.10 to 1.19; $P = .021$) for Tegner scores. Magnetic resonance imaging scans performed 1 year after surgical intervention showed significantly better MOCART scores for the cell-recipient group. The age-adjusted mean difference in MOCART score was 19.6 (95% CI, 10.5 to 28.6; $P < .001$). Conclusions Intra-articular injection of cultured MSCs is effective in improving both short-term clinical and MOCART outcomes in patients undergoing HTO and microfracture for varus knees with cartilage defects. Level of Evidence Level II, randomized controlled trial. 2013 by the Arthroscopy Association of North America.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/279/CN-00911279/frame.html>

Record #58 of 370



ID: CN-00911330

AU: Karlsson JA

AU: Neovius M

AU: Nilsson J-A

AU: Petersson IF

AU: Bratt J

AU: Vollenhoven RF

AU: Ernestam S

AU: Geborek P

TI: Addition of infliximab compared with addition of sulfasalazine and hydroxychloroquine to methotrexate in early rheumatoid arthritis: 2-year quality-of-life results of the randomised, controlled, SWEFOT trial.

SO: Annals of the Rheumatic Diseases

YR: 2013

VL: 72

NO: 12

PG: 1927-1933

XR: EMBASE 2013712766

KY: adult // article // combination chemotherapy // comparative effectiveness // controlled study // disease activity // dose response // drug dose increase // drug efficacy // drug substitution // drug withdrawal // female // follow up // human // major clinical study // male // monotherapy // priority journal // *quality of life // randomized controlled trial // *rheumatoid arthritis/dr [Drug Resistance] // *rheumatoid arthritis/dt [Drug Therapy] // treatment duration // treatment outcome // unspecified side effect/si [Side Effect] // cyclosporin A/ct [Clinical Trial] // cyclosporin A/dt [Drug Therapy] // etanercept/ae [Adverse Drug Reaction] // etanercept/ct [Clinical Trial] // etanercept/dt [Drug Therapy] // etanercept/sc [Subcutaneous Drug Administration] // *hydroxychloroquine/ae [Adverse Drug Reaction] // *hydroxychloroquine/ct [Clinical Trial] // *hydroxychloroquine/cb [Drug Combination] // *hydroxychloroquine/cm [Drug Comparison] // *hydroxychloroquine/do [Drug Dose] // *hydroxychloroquine/dt [Drug Therapy] // *hydroxychloroquine/po [Oral Drug Administration] // *infliximab/ct [Clinical Trial] // *infliximab/cb [Drug Combination] // *infliximab/cm [Drug Comparison] // *infliximab/do [Drug Dose] // *infliximab/dt [Drug Therapy] // *infliximab/iv [Intravenous Drug Administration] // *methotrexate/ct [Clinical Trial] // *methotrexate/cb [Drug Combination] // *methotrexate/do [Drug Dose] // *methotrexate/dt [Drug Therapy] // *methotrexate/po [Oral Drug Administration] // *salazosulfapyridine/ae [Adverse Drug Reaction] // *salazosulfapyridine/ct [Clinical Trial] // *salazosulfapyridine/cb [Drug Combination] // *salazosulfapyridine/cm [Drug Comparison] // *salazosulfapyridine/do [Drug Dose] // *salazosulfapyridine/po [Oral Drug Administration]

DOI: <http://dx.doi.org/10.1136/annrheumdis-2012-202062>

AB: Objective: To compare EuroQol 5-Dimensions (EQ-5D) utility and quality-adjusted life-years (QALYs) in patients with early, methotrexate (MTX) refractory rheumatoid arthritis (RA), randomised to addition of infliximab (IFX) or sulfasalazine and hydroxychloroquine (SSZ+HCQ). Methods: RA-patients with symptoms <1 year were enrolled between 2002 and 2005 at 15 Swedish centres. After 3-4 months of MTX monotherapy, patients with a remaining DAS28>3.2 were randomised to addition of IFX or SSZ+HCQ and followed for 21 months. EQ-5D profiles were collected every 3 months. Between-group comparisons of utility change and accumulated QALYs were performed, using last observation carried forward (LOCF) following protocol breach. Missing data were imputed by linear interpolation or LOCF. Sensitivity analyses applying baseline observation carried forward (BOCF) or restricted to completers were conducted. Results: Of 487 patients initially enrolled, 128 and 130 were randomised to IFX or SSZ+HCQ, respectively. Mean utility in the IFX and SSZ+HCQ groups increased from 0.52 (SD 0.27) and 0.55 (SD 0.27) at randomisation to 0.66 (SD 0.25) and 0.63 (SD 0.27) at 21

months (adjusted mean difference favouring IFX 0.04; 95% CI -0.01, 0.09; $p=0.15$). Average accumulated QALYs were 1.10 (SD 0.37) and 1.07 (SD 0.42) in the IFX and SSZ+HCQ groups, respectively (adjusted mean difference favouring IFX 0.07; 95%CI -0.01, 0.14; $p=0.07$). BOCF analysis showed similar results, while differences were reversed, though remained statistically non-significant among completers. Dropout rates in the IFX/SSZ+HCQ groups were 30%/43% ($p=0.01$). Conclusions Comparing addition of IFX or SSZ+HCQ to MTX in active early RA, no statistically significant differences in utility or QALY gain could be detected over 21 months.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/330/CN-00911330/frame.html>

Record #59 of 370



ID: CN-00960231

AU: Bonnick S

AU: Villiers T

AU: Odio A

AU: Palacios S

AU: Chapurlat R

AU: DaSilva C

AU: Scott BB

AU: Tillegheem CLBD

AU: Leung AT

AU: Gurner D

TI: Effects of odanacatib on BMD and safety in the treatment of osteoporosis in postmenopausal women previously treated with alendronate: A randomized placebo-Controlled trial.

SO: Journal of clinical endocrinology and metabolism

YR: 2013

VL: 98

NO: 12

PG: 4727-35

XR: EMBASE 2013778899


PT: Journal: Article

KY: adult // aged // alkaline phosphatase blood level // article // *bone density // bone disease/si [Side Effect] // bone turnover // controlled study // double blind procedure // drug effect // drug efficacy // drug fatality/si [Side Effect] // drug safety // drug tolerability // drug withdrawal // female // femur fracture/si [Side Effect] // femur neck // fracture/si [Side Effect] // fracture nonunion/si [Side Effect] // hip // human // jaw osteonecrosis/si [Side Effect] // lumbar spine // major clinical study // middle aged // morphea/si [Side Effect] // multicenter study // osteolysis // patient compliance // *postmenopause osteoporosis/dt [Drug Therapy] // priority journal // protein blood level // protein urine level // randomized controlled trial // respiratory tract disease/si [Side Effect] // skin disease/si [Side Effect] // tooth disease/si [Side Effect] // *alendronic acid/dt [Drug Therapy] // alkaline phosphatase bone isoenzyme/ec [Endogenous Compound] // amino terminal telopeptide/ec [Endogenous Compound] // calcium/dt [Drug Therapy] // carboxy terminal telopeptide/ec [Endogenous Compound] // colecalciferol/dt [Drug Therapy] // creatinine/ec [Endogenous Compound] // *odanacatib/ae [Adverse Drug Reaction] // *odanacatib/ct [Clinical Trial] // *odanacatib/dt [Drug Therapy] // *odanacatib/pd [Pharmacology] // placebo

DOI: 10.1210/jc.2013-2020

AB: Context: Odanacatib (ODN) is a selective cathepsin K inhibitor being developed to treat osteoporosis. Objective: The effects of ODN were evaluated on bone mineral density (BMD), biochemical markers of bone turnover, and safety in patients previously treated with alendronate. Design: This was a randomized, double-blind, placebo-controlled, 24-month study. Setting: The study was conducted at private or institutional practices. Participants: Postmenopausal women (n = 243) >60 years of age with low BMD at the total hip, femoral neck, or trochanter (T-score < -2.5 but > -3.5 without prior fracture or < -1.5 but > -3.5 with prior fracture) on alendronate for >3 years. Intervention: The intervention included ODN 50 mg or placebo weekly. Main Outcome Measures: The primary end point was percentage change from baseline of femoral neck BMD at month 24. BMD was assessed by dual-energy x-ray absorptiometry at baseline and 6, 12, and 24 months. Biochemical markers of bone turnover (serum C-telopeptides of type 1 collagen, urinary N-telopeptides of type 1 collagen, serum bone specific alkaline phosphatase, and serum N-terminal propeptide of type 1 collagen) were measured at baseline and 3, 6, 12, 18, and 24 months. Results: In the ODN group, BMD changes from baseline at the femoral neck, trochanter, total hip, and lumbar spine at 24 months (1.7%, 1.8%, 0.8%, and 2.3%, respectively) were significantly different from the placebo group. ODN significantly decreased urinary N-telopeptides of type 1 collagen to creatinine ratio and significantly increased serum N-terminal propeptide of type 1 collagen compared with placebo. Serum C-telopeptides of type 1 collagen was unexpectedly increased with ODN treatment. The safety profile appeared similar between groups. Conclusions: ODN provided incremental BMD gains in osteoporotic women after alendronate treatment. 2013 by The Endocrine Society.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/231/CN-00960231/frame.html>

Record #60 of 370 

ID: CN-00961334

AU: Follett PA

AU: Wall M

AU: Bailey W

TI: Influence of Modified Atmosphere Packaging on Radiation Tolerance in the Phytosanitary Pest Melon Fly (Diptera: Tephritidae).

SO: Journal of economic entomology

YR: 2013

VL: 106

NO: 5

PG: 2020-6

PM: PUBMED 24224242

XR: EMBASE 24224242

PT: Journal: Article

KY: animal // article // Carica // controlled clinical trial // controlled study // growth, development and aging // insect // insect control // larva // Mediterranean fruit fly // metabolism // packaging // physiology // *radiation dose // radiation exposure // randomized controlled trial // *Tephritidae // *oxygen

DOI: 10.1603/EC13117

AB: Modified atmosphere packaging (MAP) produces a low-oxygen (O_2) environment that can increase produce shelf life by decreasing product respiration and growth of pathogens. However, low O_2 is known to increase insect tolerance to irradiation, and the use of MAP with products treated by irradiation before export to control quarantine pests may inadvertently compromise treatment efficacy. Melon fly, *Bactrocera cucurbitae* Coquillett (Diptera: Tephritidae), is an important economic and quarantine pest of tropical fruits and vegetables, and one of the most radiation-tolerant tephritid fruit flies known. The effect of low O_2 generated by MAP on the radiation tolerance of *B. cucurbitae* was examined. Third-instar larval *B. cucurbitae* were inoculated into ripe papayas and treated by 1) MAP + irradiation, 2) irradiation alone, 3) MAP alone, or (4) no MAP and no irradiation, and held for adult emergence. Three types of commercially available MAP products

were tested that produced O₂ concentrations between 1 and 15%, and a sublethal radiation dose (50 Gy) was used to allow comparisons between treatments. Ziploc storage bags (1-4% O₂) increased survivorship to adult from 14 to 25%, whereas Xtend PP61 bags (3-8% O₂) and Xtend PP53 bags (11-15% O₂) did not enhance survivorship to the adult stage in *B. cucurbitae* irradiated at 50 Gy. Radiation doses approved by the United States Department of Agriculture and the International Plant Protection Commission for *B. cucurbitae* and *Ceratitis capitata* (Wiedemann) (Mediterranean fruit fly) are 150 and 100 Gy, respectively. In large-scale tests, 9,000 *B. cucurbitae* and 3,800 *C. capitata* larvae infesting papayas in Ziploc bags were irradiated at 150 and 100 Gy, respectively, with no survivors to the adult stage. MAP can increase insect survivorship during irradiation treatment at certain doses and O₂ concentrations, but should not compromise the efficacy of the 150-Gy generic radiation treatment for tephritid fruit flies or the 100-Gy radiation treatment for *C. capitata*.

US: <http://onlinelibrary.wiley.com/doi/cochrane/central/articles/334/CN-00961334/frame.html>

Record #61 of 370



ID: CN-00911654

AU: Bao T

AU: Cai L

AU: Giles JT

AU: Gould J

AU: Tarpinian K

AU: Betts K

AU: Medeiros M

AU: Jeter S

AU: Tait N

AU: Chumsri S

AU: Armstrong DK

AU: Tan M

AU: Folkard E

AU: Dowsett M

AU: Singh H

AU: Tkaczuk K

AU: Stearns V

TI: A dual-center randomized controlled double blind trial assessing the effect of acupuncture in reducing musculoskeletal symptoms in breast cancer patients taking aromatase inhibitors.

SO: Breast Cancer Research and Treatment

YR: 2013

VL: 138

NO: 1

PG: 167-174

XR: EMBASE 2013143255

KY: *acupuncture // adult // aged // article // *breast cancer/dt [Drug Therapy] // cancer chemotherapy // cancer staging // clinical article // clinical effectiveness // controlled study // disease association // double blind procedure // drug safety // estradiol blood level // female // human // multicenter study // *musculoskeletal disease/si [Side Effect] // *musculoskeletal disease/th [Therapy] // pain/th [Therapy] // postmenopause // priority journal // protein blood level // randomized controlled trial // therapy effect // treatment duration // visual analog scale // anastrozole/dt [Drug Therapy] // *aromatase inhibitor/ae [Adverse Drug Reaction] // *aromatase inhibitor/dt [Drug Therapy] // beta endorphin/ec [Endogenous Compound] // estradiol/ec [Endogenous Compound] // exemestane/dt [Drug Therapy] // gamma interferon/ec [Endogenous Compound] // interleukin 1/ec [Endogenous Compound] // interleukin 10/ec [Endogenous Compound] // interleukin 12/ec [Endogenous Compound] // interleukin 17/ec [Endogenous Compound] // interleukin 6/ec [Endogenous Compound] // interleukin 8/ec [Endogenous Compound] // letrozole/dt [Drug Therapy] // tumor necrosis factor alpha/ec [Endogenous Compound]

DOI: <http://dx.doi.org/10.1007/s10549-013-2427-z>

AB: Up to 50 % of women receiving aromatase inhibitor (AI) complain of AI-associated musculoskeletal symptoms (AIMSS) and 15 % discontinue treatment. We conducted a randomized, sham-controlled trial to evaluate whether acupuncture improves AIMSS and to explore potential mechanisms. Postmenopausal women with early stage breast cancer, experiencing AIMSS were randomized to eight weekly real or sham acupuncture sessions. We evaluated changes in the Health Assessment Questionnaire Disability Index (HAQ-DI) and pain visual analog scale (VAS) following the intervention compared to baseline. Serum estradiol, beta-endorphin, and proinflammatory cytokine concentrations were measured pre and post-intervention. We enrolled 51 women of whom 47 were evaluable, including 23 randomized to real and 24 to sham acupuncture. Baseline characteristics were balanced between groups with the exception of a higher HAQ-DI score in the real acupuncture group ($p = 0.047$). We did not

observe a statistically significant difference in reduction of HAQ-DI ($p = 0.30$) or VAS ($p = 0.31$) between the two groups. Following eight weekly treatments, we observed a statistically significant reduction of IL-17 ($p \leq 0.009$) in both groups. No significant modulation was seen in estradiol, beta-endorphin, or other proinflammatory cytokine concentrations in either group. We did not observe a significant difference in AIMSS changes between real and sham acupuncture. As sham acupuncture used in this study may not be equivalent to placebo, further studies with a non-acupuncture arm may be required to establish whether acupuncture is beneficial for the treatment of AIMSS. 2013 Springer Science+Business Media New York.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/654/CN-00911654/frame.html>

Record #62 of 370



ID: CN-00911865

AU: Cook CE

AU: Learman KE

AU: O'Halloran BJ

AU: Showalter CR

AU: Kabbaz VJ

AU: Goode AP

AU: Wright AA

TI: Which prognostic factors for low back pain are generic predictors of outcome across a range of recovery domains?

SO: Physical therapy

YR: 2013

VL: 93

NO: 1

PG: 32-40

PM: PUBMED 22879443

XR: EMBASE 22879443

PT: Journal: Article

KY: Adolescent;Decision Support Techniques;Disability Evaluation;Linear Models;Logistic Models;Low Back Pain [physiopathology] [therapy];Physical Therapy Modalities;Poisson Distribution;Predictive Value of Tests;Prognosis;Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

DOI: 10.2522/ptj.20120216

AB: BACKGROUND: Recovery from low back pain (LBP) is multidimensional and requires the use of multiple-response (outcome) measures to fully reflect these many dimensions. Predictive prognostic variables that are present or stable in all or most predictive models that use different outcome measures could be considered "universal" prognostic variables. OBJECTIVE: The aim of this study was to explore the potential of universal prognostic variables in predictive models for 4 different outcome measures in patients with mechanical LBP. DESIGN: Predictive modeling was performed using data extracted from a randomized controlled trial. Four prognostic models were created using backward stepwise deletion logistic, Poisson, and linear regression. METHODS: Data were collected from 16 outpatient physical therapy facilities in 10 states. All 149 patients with LBP were treated with manual therapy and spine strengthening exercises until discharge. Four different measures of response were used: Oswestry Disability Index and Numeric Pain Rating Scale change scores, total visits, and report of rate of recovery. RESULTS: The set of statistically significant predictors was dependent on the definition of response. All regression models were significant. Within both forms of the 4 models, meeting the clinical prediction rule for manipulation at baseline was present in all 4 models, whereas no irritability at baseline and diagnosis of sprains and strains were present in 2 of 4 of the predictive models. LIMITATIONS: The primary limitation is that this study evaluated only 4 of the multiple outcome measures that are pertinent for patients with LBP. CONCLUSIONS: Meeting the clinical prediction rule was prognostic for all outcome measures and should be considered a universal prognostic predictor. Other predictive variables were dependent on the outcomes measure used in the predictive model.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/865/CN-00911865/frame.html>

Record #63 of 370



ID: CN-00914336

AU: Sequeira PA

AU: Montoya L

AU: Ruelas V

AU: Xing D

AU: Chen V

AU: Beck R

AU: Peters AL

TI: Continuous glucose monitoring pilot in low-income type 1 diabetes patients.

SO: Diabetes technology & therapeutics

YR: 2013

VL: 15

NO: 10

PG: 855-8

XR: EMBASE 2013601307

PT: Journal: Article


KY: adult // aged // article // *blood glucose monitoring // clinical article // *continuous glucose monitoring // controlled study // crossover procedure // educational status // female // glucose blood level // Hispanic // human // *insulin dependent diabetes mellitus/dt [Drug Therapy] // intensive care // *lowest income group // male // priority journal // randomized controlled trial // carbohydrate/ec [Endogenous Compound] // hemoglobin A1c/ec [Endogenous Compound] // insulin/ct [Clinical Trial] // insulin/dt [Drug Therapy]

DOI: 10.1089/dia.2013.0072

AB: Background: Continuous glucose monitoring (CGM) has been shown to be a valuable tool to improve glycemic control in patients with diabetes. The objective of this pilot study was to develop and implement CGM in an existing diabetes clinic for low-income patients on multiple daily injections. Subjects and Methods: This was a single-center, prospective, randomized controlled, crossover pilot study. Initial focus groups were held to create low-literacy, Spanish and English guides to the use of carbohydrate counting and CGM. These tools were implemented to train participants on carbohydrate counting and insulin adjustments participants. Subjects were then randomized to start in Group A (CGM) or Group B (self-monitoring blood glucose and then switched after 28 weeks). Hemoglobin A1c (HbA1c) was obtained at baseline and at the end of both study phases. Results: Twenty-five economically challenged, primarily Latino participants with minimal prior education on intensive diabetes management completed the study. No significant reduction in HbA1c or decrease in time spent in parameters of low and high blood glucose was shown. However, eighty percent of participants who completed the study wanted to continue to use CGM once the research study was over. The participants also felt that the CGM made adjusting insulin easier. Conclusions: CGM can be implemented in patients from a low-income public clinic; however, HbA1c reduction was not achieved. Given the underlying lack of baseline self-management

knowledge, a longer trial might be necessary to see benefit with CGM in this population. 2013
Mary Ann Liebert, Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/336/CN-00914336/frame.html>

Record #64 of 370 

ID: CN-00961498

AU: Tavassoli N

AU: Perrin A

AU: Berard E

AU: Gillette S

AU: Vellas B

AU: Rolland Y

TI: Factors associated with undertreatment of atrial fibrillation in geriatric outpatients with Alzheimer disease.

SO: American journal of cardiovascular drugs

YR: 2013

VL: 13

NO: 6

PG: 425-33

XR: EMBASE 2013800944

PT: Journal: Article


KY: ADL disability // aged // *Alzheimer disease/dt [Drug Therapy] // anticoagulant therapy // article // body mass // *cardiovascular risk // caregiver // cerebrovascular accident // cognition // cohort analysis // comorbidity // congestive heart failure // controlled clinical trial // controlled study // demography // diabetes mellitus // disease association // educational status // fall risk assessment // female // gastrointestinal disease // *geriatric patient // *heart atrium fibrillation/dt [Drug Therapy] // home care // human // hypertension // kidney failure // Lawton instrumental activities of daily living scale // major clinical study // male // medical history // multicenter study // outcome assessment // outpatient // priority journal // rating scale // scoring system // very elderly // anticoagulant agent/ct [Clinical Trial] // anticoagulant

agent/cb [Drug Combination] // anticoagulant agent/cm [Drug Comparison] // anticoagulant agent/dt [Drug Therapy] // anticoagulant agent/po [Oral Drug Administration] // antiinflammatory agent // antithrombocytic agent/ct [Clinical Trial] // antithrombocytic agent/cb [Drug Combination] // antithrombocytic agent/cm [Drug Comparison] // antithrombocytic agent/dt [Drug Therapy] // donepezil/dt [Drug Therapy] // galantamine/dt [Drug Therapy] // rivastigmine/dt [Drug Therapy]

DOI: 10.1007/s40256-013-0040-5

AB: Background: According to international recommendations [from the American College of Cardiology/American Heart Association/European Society of Cardiology] and those of the Haute Autorite de Sante (HAS) in France, treatment with a vitamin K antagonist is recommended in patients with atrial fibrillation (AF) in the presence of a high thromboembolic risk factor [history of stroke, transient ischemic attack, systemic embolism, or valvular heart disease, or presence of a mechanical heart valve prosthesis] or at least two moderate risk factors (age >75 years, hypertension, congestive heart failure, or diabetes). In patients with a major contraindication, the vitamin K antagonist can be replaced by an antiplatelet agent (APA). These recommendations are not systematically observed in patients with Alzheimer disease (AD). The aim of our study was to determine the factors associated with undertreatment of AF in geriatric outpatients with AD. **Methods:** Use of oral anticoagulants or APAs was studied in 66 patients with AF who were included in the French Network on Alzheimer Disease (REAL.FR) cohort, consisting of 686 outpatients living at home, supported by an informal caregiver, and suffering from Alzheimer-type dementia, with a Mini Mental Status Examination (MMSE) score between 10 and 26. First, demographic characteristics (age, sex, body mass index [BMI], living arrangements, educational level), medical conditions (comorbidity, number of medications), disability (activities of daily living [ADL], instrumental activities of daily living [IADL]), risk of falls (one-leg balance test), cognitive status (according to MMSE, Alzheimer's Disease Assessment Scale - Cognitive Subscale [ADAS-Cog], and Clinical Dementia Rating [CDR] scores), risk factors for stroke (hypertension, history of stroke, congestive heart failure, diabetes, or age >75 years) and potential contraindications to oral anticoagulants (OACs) or APAs (polypharmacy, risk of falls, renal failure, gastrointestinal diseases) of patients receiving OACs were compared with those of patients receiving APAs and those of patients receiving no treatment for AF. Then the same characteristics were compared between patients receiving no treatment for AF and those receiving OACs or APAs. **Results:** Only 56 % (n = 37) of patients with AF were receiving OACs or APAs at the baseline visit, of whom 18 (49 %) were receiving OACs and 19 (51 %) were receiving APAs. Bivariate analysis showed that patients receiving OACs or APAs were significantly more likely to have a history of cardiovascular disease (p = 0.005) - in particular, hypertension (p = 0.037) - less likely to be living alone and unaided (p = 0.038), and less likely to be taking nonsteroidal anti-inflammatory drugs [NSAIDs] (p = 0.001). **Conclusion:** Despite the national and international recommendations, nearly half of AD patients with AF do not receive OACs or APAs. A history of cardiovascular disease - in particular, hypertension - improves access to treatment, but use of NSAIDs and living alone without home care seem to be the main factors associated with non-prescription of OACs or APAs. 2013 Springer International Publishing Switzerland.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/498/CN-00961498/frame.html>

Record #65 of 370 

ID: CN-00813969

AU: Howard R

AU: McShane R

AU: Lindsay J

AU: Ritchie C

AU: Baldwin A

AU: Barber R

AU: Burns A

AU: Dening T

AU: Findlay D

AU: Holmes C

AU: Hughes A

AU: Jacoby R

AU: Jones R

AU: Jones R

AU: McKeith I

AU: Macharouthu A

AU: O'Brien J

AU: Passmore P

AU: Sheehan B

AU: Juszczak E

AU: Katona C

AU: Hills R

AU: Knapp M

AU: Ballard C

AU: Brown R

AU: Banerjee S

AU: Onions C

AU: Griffin M

AU: Adams J

AU: Gray R

AU: Johnson T

AU: Bentham P

AU: Phillips P

TI: Donepezil and memantine for moderate-to-severe Alzheimer's disease.

SO: The New England journal of medicine

YR: 2012

VL: 366

NO: 10

PG: 893-903

PM: PUBMED 22397651

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Double-Blind Method;Drug Synergism;Drug Therapy, Combination;Excitatory Amino Acid Antagonists [adverse effects] [therapeutic use];Indans [adverse effects] [therapeutic use];Kaplan-Meier Estimate;Memantine [adverse effects] [therapeutic use];Patient Dropouts;Piperidines [adverse effects] [therapeutic use];Psychological Tests;Receptors, N-Methyl-D-Aspartate [antagonists & inhibitors];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]


CC: SR-DEMENTIA

DOI: 10.1056/NEJMoa1106668

AB: BACKGROUND: Clinical trials have shown the benefits of cholinesterase inhibitors for the treatment of mild-to-moderate Alzheimer's disease. It is not known whether treatment

benefits continue after the progression to moderate-to-severe disease. **METHODS:** We assigned 295 community-dwelling patients who had been treated with donepezil for at least 3 months and who had moderate or severe Alzheimer's disease (a score of 5 to 13 on the Standardized Mini-Mental State Examination [SMMSE, on which scores range from 0 to 30, with higher scores indicating better cognitive function]) to continue donepezil, discontinue donepezil, discontinue donepezil and start memantine, or continue donepezil and start memantine. Patients received the study treatment for 52 weeks. The coprimary outcomes were scores on the SMMSE and on the Bristol Activities of Daily Living Scale (BADLS, on which scores range from 0 to 60, with higher scores indicating greater impairment). The minimum clinically important differences were 1.4 points on the SMMSE and 3.5 points on the BADLS. **RESULTS:** Patients assigned to continue donepezil, as compared with those assigned to discontinue donepezil, had a score on the SMMSE that was higher by an average of 1.9 points (95% confidence interval [CI], 1.3 to 2.5) and a score on the BADLS that was lower (indicating less impairment) by 3.0 points (95% CI, 1.8 to 4.3) ($P<0.001$ for both comparisons). Patients assigned to receive memantine, as compared with those assigned to receive memantine placebo, had a score on the SMMSE that was an average of 1.2 points higher (95% CI, 0.6 to 1.8; $P<0.001$) and a score on the BADLS that was 1.5 points lower (95% CI, 0.3 to 2.8; $P=0.02$). The efficacy of donepezil and of memantine did not differ significantly in the presence or absence of the other. There were no significant benefits of the combination of donepezil and memantine over donepezil alone. **CONCLUSIONS:** In patients with moderate or severe Alzheimer's disease, continued treatment with donepezil was associated with cognitive benefits that exceeded the minimum clinically important difference and with significant functional benefits over the course of 12 months. (Funded by the U.K. Medical Research Council and the U.K. Alzheimer's Society; Current Controlled Trials number, ISRCTN49545035.).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/969/CN-00813969/frame.html>

Record #66 of 370 

ID: CN-00468084

AU: Courtney C

AU: Farrell D

AU: Gray R

AU: Hills R

AU: Lynch L

AU: Sellwood E

AU: Edwards S

AU: Hardyman W

AU: Raftery J

AU: Crome P

AU: Lendon C

AU: Shaw H

AU: Bentham P

TI: Long-term donepezil treatment in 565 patients with Alzheimer's disease (AD2000): randomised double-blind trial.

SO: Lancet

YR: 2012

VL: 363

NO: 9427

PG: 2105-15

PM: PUBMED 15220031

XR: EMBASE 2004278082

PT: Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [diagnosis] [drug therapy] [economics];Cholinesterase Inhibitors [adverse effects] [economics] [therapeutic use];Cognition;Cost-Benefit Analysis;Disease Progression;Double-Blind Method;Great Britain;Health Care Costs;Health Resources [utilization];Indans [adverse effects] [economics] [therapeutic use];Institutionalization;Piperidines [adverse effects] [economics] [therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1016/S0140-6736(04)16499-4

AB: BACKGROUND: Cholinesterase inhibitors produce small improvements in cognitive and global assessments in Alzheimer's disease. We aimed to determine whether donepezil produces worthwhile improvements in disability, dependency, behavioural and psychological symptoms, carers' psychological wellbeing, or delay in institutionalisation. If so, which patients benefit, from what dose, and for how long? METHODS: 565 community-resident patients with mild to moderate Alzheimer's disease entered a 12-week run-in period in which they were

randomly allocated donepezil (5 mg/day) or placebo. 486 who completed this period were rerandomised to either donepezil (5 or 10 mg/day) or placebo, with double-blind treatment continuing as long as judged appropriate. Primary endpoints were entry to institutional care and progression of disability, defined by loss of either two of four basic, or six of 11 instrumental, activities on the Bristol activities of daily living scale (BADLS). Outcome assessments were sought for all patients and analysed by logrank and multilevel models. FINDINGS: Cognition averaged 0.8 MMSE (mini-mental state examination) points better (95% CI 0.5-1.2; $p<0.0001$) and functionality 1.0 BADLS points better (0.5-1.6; $p<0.0001$) with donepezil over the first 2 years. No significant benefits were seen with donepezil compared with placebo in institutionalisation (42% vs 44% at 3 years; $p=0.4$) or progression of disability (58% vs 59% at 3 years; $p=0.4$). The relative risk of entering institutional care in the donepezil group compared with placebo was 0.97 (95% CI 0.72-1.30; $p=0.8$); the relative risk of progression of disability or entering institutional care was 0.96 (95% CI 0.74-1.24; $p=0.7$). Similarly, no significant differences were seen between donepezil and placebo in behavioural and psychological symptoms, carer psychopathology, formal care costs, unpaid caregiver time, adverse events or deaths, or between 5 mg and 10 mg donepezil. INTERPRETATION: Donepezil is not cost effective, with benefits below minimally relevant thresholds. More effective treatments than cholinesterase inhibitors are needed for Alzheimer's disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/084/CN-00468084/frame.html>

Record #67 of 370



ID: CN-00612372

AU: Howard RJ

AU: Juszczak E

AU: Ballard CG

AU: Bentham P

AU: Brown RG

AU: Bullock R

AU: Burns AS

AU: Holmes C

AU: Jacoby R

AU: Johnson T

AU: Knapp M

AU: Lindesay J

AU: O'Brien JT

AU: Wilcock G

AU: Katona C

AU: Jones RW

AU: DeCesare J

AU: Rodger M

TI: Donepezil for the treatment of agitation in Alzheimer's disease.

SO: The New England journal of medicine

YR: 2012

VL: 357

NO: 14

PG: 1382-92

PM: PUBMED 17914039

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [psychology];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Double-Blind Method;Indans [adverse effects] [therapeutic use];Piperidines [adverse effects] [therapeutic use];Psychomotor Agitation [drug therapy] [etiology] [therapy];Psychotherapy;Social Support;Treatment Failure;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]


CC: SR-DEMENTIA

DOI: 10.1056/NEJMoa066583

AB: BACKGROUND: Agitation is a common and distressing symptom in patients with Alzheimer's disease. Cholinesterase inhibitors improve cognitive outcomes in such patients, but the benefits of these drugs for behavioral disturbances are unclear. METHODS: We randomly assigned 272 patients with Alzheimer's disease who had clinically significant agitation and no response to a brief psychosocial treatment program to receive 10 mg of donepezil per day (128 patients) or placebo (131 patients) for 12 weeks. The primary outcome was a change in the score on the Cohen-Mansfield Agitation Inventory (CMAI) (on a scale of 29 to 203, with higher scores indicating more agitation) at 12 weeks. RESULTS: There was no significant difference between the effects of donepezil and those of placebo on the basis of the change in CMAI scores from baseline to 12 weeks (estimated mean difference in change [the

value for donepezil minus that for placebo], -0.06; 95% confidence interval [CI], -4.35 to 4.22). Twenty-two of 108 patients (20.4%) in the placebo group and 22 of 113 (19.5%) in the donepezil group had a reduction of 30% or greater in the CMAI score (the value for donepezil minus that for placebo, -0.9 percentage point; 95% CI, -11.4 to 9.6). There were also no significant differences between the placebo and donepezil groups in scores for the Neuropsychiatric Inventory, the Neuropsychiatric Inventory Caregiver Distress Scale, or the Clinician's Global Impression of Change. CONCLUSIONS: In this 12-week trial, donepezil was not more effective than placebo in treating agitation in patients with Alzheimer's disease. (ClinicalTrials.gov number, NCT00142324 [ClinicalTrials.gov].).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/372/CN-00612372/frame.html>

Record #68 of 370 

ID: CN-00718613

AU: Brodaty H

AU: Mittelman M

AU: Gibson L

AU: Seeher K

AU: Burns A

TI: The effects of counseling spouse caregivers of people with Alzheimer disease taking donepezil and of country of residence on rates of admission to nursing homes and mortality.

SO: The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry

YR: 2012

VL: 17

NO: 9

PG: 734-43

PM: PUBMED 19705519

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [mortality] [nursing] [psychology];Australia;Caregivers [psychology];Cholinesterase Inhibitors [therapeutic use];Counseling [methods];Great Britain;Homes for the Aged [utilization];Indans [therapeutic use];Institutionalization [statistics]

& numerical data];Nursing Homes [utilization];Piperidines [therapeutic use];Questionnaires;Social Support;Spouses [psychology];United States;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-BEHAVMED: SR-DEMENTIA

AB: OBJECTIVE: Does psychosocial intervention for caregivers whose spouses with Alzheimer disease (AD) are taking donepezil delay nursing home (NH) placement or death of patients? DESIGN: Randomized controlled trial with 2 years of active treatment and up to 8.5 years of follow-up (mean: 5.4 years, SD: 2.4). SETTING: Outpatients of research clinics in Australia, the United Kingdom, and the United States. PARTICIPANTS: One hundred and fifty-five persons with AD and their spouses. INTERVENTION: Five sessions of individual and family counseling (+ prn ad hoc counseling) or usual care. MEASUREMENTS: Time to institutionalization and death using Cox proportional hazards methods. RESULTS: Over a mean of 5.4 years (SD: 2.4), there were no differences in NH placement or mortality by intervention group, but there were by country, with Australian patients admitted to NHs earlier than U.S. than U.K. patients. CONCLUSION: Earlier NH admission of Australian compared to U.K. and U.S. subjects may be due to differences in health care, NH systems, availability, and affordability.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/613/CN-00718613/frame.html>

Record #69 of 370



ID: CN-00767062

AU: Bergman J

AU: Brettholz I

AU: Shneidman M

AU: Lerner V

TI: Addition of donepezil for treatment of psychotic symptoms in patients with dementia of the alzheimerâ??s type

SO: International Psychogeriatrics

YR: 2012

VL: 15

NO: Suppl 2

CC: HS-SCHIZ: HS-HANDSRCH: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/062/CN-00767062/frame.html>

Record #70 of 370



ID: CN-00669609

AU: Mittelman MS

AU: Brodaty H

AU: Wallen AS

AU: Burns A

TI: A three-country randomized controlled trial of a psychosocial intervention for caregivers combined with pharmacological treatment for patients with Alzheimer disease: effects on caregiver depression.

SO: The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry

YR: 2012

VL: 16

NO: 11

PG: 893-904

PM: PUBMED 18978250

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't


KY: Alzheimer Disease [drug therapy] [nursing] [psychology];Australia;Caregivers [psychology];Cholinesterase Inhibitors [therapeutic use];Counseling [methods];Depression [psychology];Family Therapy;Great Britain;Indans [therapeutic use];Linear Models;Longitudinal Studies;Piperidines [therapeutic use];Questionnaires;Social Support;Spouses [psychology];United States;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-BEHAVMED: SR-DEMENTIA

DOI: 10.1097/JGP.0b013e3181898095

AB: OBJECTIVE: To evaluate the effectiveness of a combination of cholinesterase inhibitor therapy for patients with Alzheimer disease (AD) and psychosocial intervention, for their spouse caregivers compared with drug treatment alone in three countries simultaneously. DESIGN: Randomized controlled trial. Structured questionnaires were administered at baseline and at regular follow-up intervals for 24 months by independent raters blind to group assignment. SETTING: Outpatient research clinics in New York City, U.S., Manchester, U.K. and Sydney, Australia. PARTICIPANTS: Volunteer sample of 158 spouse caregivers of community dwelling patients with AD. INTERVENTIONS: Five sessions of individual and family counseling within 3 months of enrollment and continuous availability of ad hoc telephone counseling were provided for half the caregivers. Donepezil was prescribed for all patients. MAIN OUTCOME MEASURE: Depressive symptoms of spouse caregivers measured at intake and follow-up assessments for 24 months using Beck Depression Inventory (revised). RESULTS: Depression scores of caregivers who received counseling decreased over time, whereas the depression scores for caregivers who did not receive counseling increased. The benefit of the psychosocial intervention was significant after controlling for site, gender and country was not accounted for by antidepressant use and increased over 2 years even though the individual and family counseling sessions occurred in the first 3 months. CONCLUSION: Effective counseling and support interventions can reduce symptoms of depression in caregivers when patients are taking donepezil. Harmonized multinational psychosocial interventions are feasible. Combined drug and supportive care approaches to the management of people with AD should be a priority.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/609/CN-00669609/frame.html>

Record #71 of 370 

ID: CN-00767413

AU: Nofal A

AU: Nofal E

TI: Intralesional immunotherapy of common warts: successful treatment with mumps, measles and rubella vaccine.

SO: Journal of the European Academy of Dermatology and Venereology : JEADV

YR: 2012

VL: 24

NO: 10

PG: 1166-70

PM: PUBMED 20202055

PT: Journal Article; Randomized Controlled Trial

KY: Adolescent; Follow-Up Studies; Immunotherapy; Measles-Mumps-Rubella Vaccine [adverse effects] [therapeutic use]; Recurrence; Treatment Outcome; Warts [therapy]; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]; Young Adult[checkword]

CC: SR-ARI: SR-SKIN

DOI: 10.1111/j.1468-3083.2010.03611.x

AB: BACKGROUND: Despite numerous therapeutic modalities reported in the literature, treatment of common warts remains a continuing challenge and there is no universal consensus about optimal treatment. Recently, intralesional immunotherapy by different antigens has proved efficacy in the treatment of different types of warts. OBJECTIVE: To evaluate the efficacy and safety of intralesional mumps, measles and rubella (MMR) vaccine in the treatment of common warts. METHODS: The study included 135 patients with single or multiple recalcitrant or non-recalcitrant common warts. They were randomly assigned to two groups; the first group (85 patients) received intralesional MMR vaccine, and the second group (50 patients) received intralesional saline as a control group. Both treatments were injected into single lesions or largest wart in case of multiple lesions at 2-week intervals until complete clearance or for a maximum of five treatments. Follow-up was made every 2 months for 6 months to detect any recurrence. RESULTS: A highly significant difference was found between the therapeutic response of common warts to MMR vaccine and saline control group ($P < 0.001$). In the MMR group, complete response was achieved in 80% and 84.6% of patients presenting with recalcitrant and multiple warts respectively. No recurrence was observed in the MMR group and side effects included pain during injection and flu-like symptoms. CONCLUSIONS: Intralesional immunotherapy by MMR vaccine is a promising effective and safe treatment modality for common warts, particularly the multiple ones.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/413/CN-00767413/frame.html>

Record #72 of 370



ID: CN-00003169

AU: Leutenegger A

AU: Lüthy E

TI: [A new substance in the therapy of angina pectoris: Amiodarone].

SO: Schweizerische medizinische Wochenschrift

YR: 2012

VL: 98

NO: 51

PG: 2020-5

PM: PUBMED 4889970

PT: Clinical Trial; Journal Article; Randomized Controlled Trial

KY: Angina Pectoris [drug therapy];Cardiovascular System [drug effects];Clinical Trials as Topic;Epinephrine [antagonists & inhibitors];Oxygen Consumption [drug effects];Sympatholytics [therapeutic use];Vasodilator Agents [therapeutic use];Humans[checkword]

CC: HS-HANDSRCH: SR-VASC

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/169/CN-00003169/frame.html>

Record #73 of 370



ID: CN-00842298

AU: Doody RS

AU: Geldmacher DS

AU: Farlow MR

AU: Sun Y

AU: Moline M

AU: Mackell J

TI: Efficacy and safety of donepezil 23 mg versus donepezil 10 mg for moderate-to-severe Alzheimer's disease: a subgroup analysis in patients already taking or not taking concomitant memantine.

SO: Dementia and geriatric cognitive disorders

YR: 2012

VL: 33

NO: 2-3

PG: 164-73

PM: PUBMED 22572767

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [diagnosis] [drug therapy] [psychology];Dose-Response Relationship, Drug;Double-Blind Method;Drug Therapy, Combination;Geriatric Assessment [methods];Indans [administration & dosage] [adverse effects];Intelligence Tests;Memantine [administration & dosage] [adverse effects];Piperidines [administration & dosage] [adverse effects];Psychiatric Status Rating Scales;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1159/000338236

AB: BACKGROUND/AIMS: A large multicenter trial of donepezil 23 mg/day versus donepezil 10 mg/day for moderate-to-severe Alzheimer's disease allowed patients taking concomitant memantine. We evaluated the efficacy/safety of donepezil 23 and 10 mg/day in this trial, with respect to concomitant memantine use. METHODS: Prespecified analysis of data from a 24-week, randomized, double-blind trial. Patients were randomized to donepezil doses (23 vs. 10 mg/day) and stratified by concomitant memantine use (yes or no). Efficacy and safety were assessed for each donepezil dose in subgroups taking or not taking concomitant memantine. RESULTS: At week 24, donepezil 23 mg/day provided significant cognitive benefits over 10 mg/day ($p < 0.01$) on the Severe Impairment Battery, with or without concomitant memantine (ANCOVA adjusted for baseline score, country and treatment). The higher dose showed no benefit on the global function, Mini-Mental State Examination or activities of daily living measures in either memantine subgroup. Rates of treatment-emergent adverse events (AEs) were higher for donepezil 23 mg/day with memantine (80.7%) than 23 mg/day without memantine (69.7%) or 10 mg/day with/without memantine (66.7/62.0%); across all treatment groups, most events were mild/moderate in severity. Individual rates of serious AEs were low ($<1.0\%$), regardless of concomitant memantine use. CONCLUSION: In this population, concomitant memantine use did not alter the response profile of donepezil 23 vs. 10 mg/day. Donepezil 23 mg was generally safe and well tolerated among patients receiving donepezil alone and among patients receiving a combination of donepezil and memantine therapy.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/298/CN-00842298/frame.html>

Record #74 of 370



ID: CN-00842261

AU: Li DQ

AU: Zhou YP

AU: Yang H

TI: Donepezil combined with natural hirudin improves the clinical symptoms of patients with mild-to-moderate Alzheimer's disease: a 20-week open-label pilot study.

SO: International journal of medical sciences

YR: 2012

VL: 9

NO: 3

PG: 248-55

PM: PUBMED 22606044

PT: Journal Article; Randomized Controlled Trial

KY: Activities of Daily Living;Alzheimer Disease [drug therapy] [physiopathology];Hirudins [administration & dosage];Indans [administration & dosage] [therapeutic use];Nootropic Agents [administration & dosage] [therapeutic use];Pilot Projects;Piperidines [administration & dosage] [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.7150/ijms.4363

AB: AIM: To evaluate the efficacy and safety of donepezil plus natural hirudin in patients with mild-to-moderate Alzheimer's Disease. METHODS: In the 20-week, randomized, open-label and controlled study, 84 patients received either donepezil (5 mg/day for the first 4 weeks and 10 mg/day thereafter) or donepezil plus natural hirudin (3 g/day) treatment. Efficacy was reflected by the change of the total scores of Alzheimer's Disease Assessment Scale cognitive subscale (ADAS-Cog), Activities of Daily Life (ADL) and Neuropsychiatric Inventory (NPI).

RESULTS: The patients with the donepezil plus natural hirudin treatment showed more significant improvement in the daily activities and the decline of the cognition than those with donepezil treatment. Significant difference was present in the groups since the 8th week. No group difference was found in the NPI change. However, within the hirudin treatment group, more powerful efficacy including NPI assessment was found in the patients with vascular risk factors (VRF) as comparing to with those without VRF. The combination of donepezil and natural hirudin was well tolerated. The dropout rate was greater in the donepezil and natural hirudin (50%) treatment group than in the donepezil (39%) treatment group. Similar result was found in the incidence of adverse events (23.8% vs 19.0%), but there was no statistical difference between the two groups. Adverse events were the most common reason for the dropout. Although hemorrhage and hypersensitiveness were more common in donepezil plus Maixuekang treatment (11.9% and 7.1%) group than in donepezil treatment (2.4% and 2.4%) group, no significant difference was present between the two groups. Economic problem was another important reason for the patients' withdrawal. CONCLUSIONS: Compared with the

donepezil treatment in the patients with mild-to-moderate AD, our results suggest that donepezil combined with natural hirudin may improve the treatment effects in the ADL, BPSD and cognition of the patients. Furthermore, this joint treatment is safe.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/261/CN-00842261/frame.html>

Record #75 of 370



ID: CN-00902519

AU: Dubois B

AU: Tolosa E

AU: Katzenschlager R

AU: Emre M

AU: Lees AJ

AU: Schumann G

AU: Pourcher E

AU: Gray J

AU: Thomas G

AU: Swartz J

AU: Hsu T

AU: Moline ML

TI: Donepezil in Parkinson's disease dementia: A randomized, double-blind efficacy and safety study.

SO: Movement Disorders

YR: 2012

VL: 27

NO: 10

PG: 1230-1238

XR: EMBASE 2012544946

KY: aged // Alzheimer's Disease Assessment Scale Cognitive Subscale // article // attention // behavior // brief test of attention // clinician's interview based impression of change // controlled study // daily life activity // delis kaplan executive function system // diarrhea/si [Side Effect] // disease severity // dose response // double blind procedure // *drug efficacy // *drug safety // drug tolerability // drug withdrawal // dyskinesia/si [Side Effect] // dystonia/si [Side Effect] // executive function // female // human // intention to treat analysis // laboratory test // lower respiratory tract infection/si [Side Effect] // major clinical study // male // Mini Mental State Examination // named inventories, questionnaires and rating scales // nausea/si [Side Effect] // *Parkinson disease/dt [Drug Therapy] // parkinsonism/si [Side Effect] // physical examination // priority journal // randomized controlled trial // respiratory distress/si [Side Effect] // side effect/si [Side Effect] // single drug dose // treatment duration // tremor/si [Side Effect] // vomiting/si [Side Effect] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy] // *donepezil/po [Oral Drug Administration] // placebo

DOI: <http://dx.doi.org/10.1002/mds.25098>

AB: Parkinson's disease dementia (PDD) is associated with cholinergic deficits. This report presents an efficacy and safety study of the acetylcholinesterase inhibitor donepezil hydrochloride in PDD. PDD patients (n = 550) were randomized to donepezil (5 or 10 mg) or placebo for 24 weeks. Coprimary end points were the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and Clinician's Interview-Based Impression of Change plus caregiver input (CIBIC+; global function). Secondary end points measured executive function, attention, activities of daily living (ADLs), and behavioral symptoms. Safety and tolerability were assessed. ADAS-cog mean changes from baseline to week 24 (end point) were not significant for donepezil in the intent-to-treat population by the predefined statistical model (difference from placebo: -1.45, P = .050, for 5 mg; -1.45, P = .076, for 10 mg). Alternative ADAS-cog analysis, removing the treatment-by-country interaction term from the model, revealed significant, dose-dependent benefit with donepezil (difference from placebo: -2.08, P = .002, for 5 mg; -3.31, P < .001, for 10 mg). The 10-mg group, but not the 5-mg group, had significantly better CIBIC+ scores compared with placebo (3.7 vs 3.9, P = .113, for 5 mg; 3.6 vs 3.9, P = .040, for 10 mg). Secondary end points-Mini-Mental State Exam; Delis-Kaplan Executive Function System; Brief Test of Attention, representing cognitive functions particularly relevant to PDD-showed significant benefit for both donepezil doses (P ≤ .007). There were no significant differences in ADLs or behavior. Adverse events were more common with donepezil but mostly mild/moderate in severity. Although the study did not achieve its predefined primary end points, it presents evidence suggesting that donepezil can improve cognition, executive function, and global status in PDD. Tolerability was consistent with the known safety profile of donepezil. 2012 Movement Disorder Society.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/519/CN-00902519/frame.html>

Record #76 of 370



ID: CN-00841198

AU: Salloway S

AU: Mintzer J

AU: Cummings JL

AU: Geldmacher D

AU: Sun Y

AU: Yardley J

AU: Mackell J

TI: Subgroup analysis of US and non-US patients in a global study of high-dose donepezil (23 mg) in moderate and severe Alzheimer's disease.

SO: American journal of Alzheimer's disease and other dementias

YR: 2012

VL: 27

NO: 6

PG: 421-32

PM: PUBMED 22930699

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [genetics];Analysis of Variance;Apolipoproteins E [genetics];Dopamine Agents [therapeutic use];Dose-Response Relationship, Drug;Double-Blind Method;Drug Therapy, Combination;Indans [administration & dosage] [adverse effects];Memantine [therapeutic use];Neuropsychological Tests;Nootropic Agents [administration & dosage] [adverse effects];Piperidines [administration & dosage] [adverse effects];Severity of Illness Index;United States;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]


CC: SR-DEMENTIA

DOI: 10.1177/1533317512454708

AB: To better understand responses in the large number of US-based patients included in a global trial of donepezil 23 mg/d versus 10 mg/d for moderate-to-severe Alzheimer's disease (AD), post hoc exploratory analyses were performed to assess the efficacy and safety in US and non-US (rest of the world [RoW]) patient subgroups. In both subgroups, donepezil 23 mg/d

was associated with significantly greater cognitive benefits than donepezil 10 mg/d. Significant global function benefits of donepezil 23 mg/d over 10 mg/d were also observed in the US subgroup only. Compared with RoW patients, US patients had relatively more severe AD, had been treated with donepezil 10 mg/d for longer periods prior to the start of the study, and a higher proportion took concomitant memantine. In both subgroups, donepezil had acceptable tolerability; overall incidence of treatment-emergent adverse events was higher in patients receiving donepezil 23 mg/d compared with donepezil 10 mg/d.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/198/CN-00841198/frame.html>

Record #77 of 370 

ID: CN-00842173

AU: Tariot P

AU: Salloway S

AU: Yardley J

AU: Mackell J

AU: Moline M

TI: Long-term safety and tolerability of donepezil 23 mg in patients with moderate to severe Alzheimer's disease.

SO: BMC research notes

YR: 2012

VL: 5

PG: 283

PM: PUBMED 22681723

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [physiopathology]; Ambulatory Care; Biomarkers, Pharmacological [metabolism]; Cognition [drug effects]; Dose-Response Relationship, Drug; Drug Administration Schedule; Follow-Up Studies; Indans [administration & dosage] [adverse effects]; Neuropsychological Tests; Nootropic Agents [administration & dosage] [adverse effects]; Piperidines [administration & dosage] [adverse effects]; Treatment Outcome; Aged [checkword]; Aged, 80 and

over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1186/1756-0500-5-283

AB: BACKGROUND: Donepezil (23 mg/day) is approved by the US Food and Drug Administration for the treatment of patients with moderate to severe Alzheimer's disease (AD). Approval was based on results from a 24-week, randomized, double-blind study of patients who were stable on donepezil 10 mg/day and randomized 2:1 to either increase their donepezil dose to 23 mg/day or continue taking 10 mg/day. The objective of this study was to assess the long-term safety and tolerability of donepezil 23 mg/day in patients with moderate to severe AD. METHODS: Patients who completed the double-blind study and were eligible could enroll into a 12-month extension study of open-label donepezil 23 mg/day. Clinic visits took place at open-label baseline and at months 3, 6, 9, and 12. Safety analyses comprised examination of the incidence, severity, and timing of treatment-emergent adverse events (AEs); changes in weight, electrocardiogram, vital signs, and laboratory parameters; and discontinuation due to AEs. RESULTS: 915 double-blind study completers were enrolled in the open-label extension study and 902 comprised the safety population. Mean treatment duration in this study was 10.3 ± 3.5 months. In total, 674 patients (74.7%) reported at least one AE; in 320 of these patients (47.5%) at least one AE was considered to be possibly or probably study drug related. The majority of patients reporting AEs (81.9%) had AEs of mild or moderate severity. There were 268 patients (29.7%) who discontinued early, of which 123 (13.6%) were due to AEs. Patients increasing donepezil dose from 10 mg/day in the double-blind study to 23 mg/day in the extension study had slightly higher rates of AEs and SAEs than patients who were already receiving 23 mg (78.0% and 16.9% vs 72.8% and 14.0%, respectively). The incidence of new AEs declined rapidly after the first 2 weeks and remained low throughout the duration of the study. CONCLUSION: This study shows that long-term treatment with donepezil 23 mg/day is associated with no new safety signals. The elevated incidence of AEs in patients increasing the dose of donepezil from 10 mg/day to 23 mg/day was limited to the initial weeks of the study.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/173/CN-00842173/frame.html>

Record #78 of 370



ID: CN-00843477

AU: Kasuya M

AU: Meguro K

AU: Okamura N

AU: Funaki Y

AU: Ishikawa H

AU: Tanaka N

AU: Iwata R

AU: Yanai K

TI: Greater responsiveness to donepezil in Alzheimer patients with higher levels of acetylcholinesterase based on attention task scores and a donepezil PET study.

SO: Alzheimer disease and associated disorders

YR: 2012

VL: 26

NO: 2

PG: 113-8

PM: PUBMED 21666432

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Acetylcholinesterase [metabolism];Alzheimer Disease [drug therapy] [enzymology] [physiopathology] [radionuclide imaging];Attention [physiology];Cholinesterase Inhibitors [therapeutic use];Indans [therapeutic use];Neuropsychological Tests;Piperidines [therapeutic use];Positron-Emission Tomography;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1097/WAD.0b013e3182222bc0

AB: The aim of the study was to predict donepezil responders among patients with Alzheimer disease (AD) based on cognitive tests and positron emission tomography. The Mini-Mental State Examination, Digit Symbol subtest (DigSm) of Wechsler Adult Intelligence Scale Revised, and Trail-Making Test A were administered for 80 patients with AD to assess global function, attention, and executive function, respectively. The same tests and the Clinical Global Impression (CGI) scale were conducted after treatment with oral donepezil (5 mg/d) for 6 months (study 1). [C]-Donepezil positron emission tomography examinations were conducted before and after treatment for 30 randomly selected patients. The distribution volume (DV), which indicates the density of donepezil-binding sites, was calculated using Logan graphical analysis (study 2). In study 1, 35 patients were identified as responders based on the CGI and Mini-Mental State Examination changes. These patients had higher baseline DigSm scores compared with nonresponders. In study 2, 15 patients were responders. DigSm correlated with DV at baseline. DV at baseline and %DV change in responders were higher than in nonresponders, and these variables correlated with DigSm and CGI scores. Higher baseline

attention may predict responsiveness to donepezil in patients with AD, and higher acetylcholinesterase levels result in a greater clinical effect.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/477/CN-00843477/frame.html>

Record #79 of 370 

ID: CN-00903369

AU: Howard R

TI: Donepezil or memantine improved cognitive functioning in moderate-to-severe Alzheimer disease.

SO: Annals of internal medicine

YR: 2012

VL: 156

NO: 12

PG: JC6-JC10

XR: EMBASE 2012362972

PT: Journal: Article

KY: aged // *Alzheimer disease/dt [Drug Therapy] // article // caregiver // *cognition // community living // controlled study // double blind procedure // female // human // major clinical study // male // Mini Mental State Examination // multicenter study // prescription // priority journal // randomized controlled trial // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy] // *memantine/ct [Clinical Trial] // *memantine/dt [Drug Therapy] // placebo

AB: Question In community-dwelling patients with moderate-to-severe Alzheimer disease, what are the benefits of continuing donepezil and/or initiating memantine treatment?

Methods Design: Randomized, 2 x 2 factorial, placebo-controlled trial (Donepezil and Memantine in Moderate to Severe Alzheimer's Disease [DOMINO] study). Current Controlled Trials ISRCTN49545035. Allocation: Concealed.* Blinding: Blinded* (patients, clinicians, outcome assessors, and {trialists}+). Follow-up period: 30 weeks. Follow-up at 1 year was < 80% (results not reported in this abstract). Setting: {14 clinical centers in the UK.}+ Patients: 295 community-dwelling residents (mean age 77 y, 65% women) who had probable or possible moderate or severe Alzheimer disease, had been prescribed donepezil for > 3 continuous months at a dose of 10 mg for > 6 previous weeks, and scored 5 to 13 on the Standardized Mini-Mental State Examination (SSMSE). Eligible patients had caregivers who lived with them or visited them daily, and their clinicians were considering changing their drug treatments.

Exclusion criteria included severe or unstable medical conditions and use of memantine. Intervention: Continuation of donepezil with placebo memantine (n = 73), continuation of donepezil plus memantine (n = 73), discontinuation of donepezil plus placebo memantine (n = 73), or discontinuation of donepezil plus memantine (n = 76). Memantine was initiated in week 1 at a dose of 5 mg and increased weekly by 5-mg increments to a dose of 20 mg in week 4. Outcomes: Cognitive (SMMSE) and functional (Bristol Activities of Daily Living Scale [BADLS]) scores. Patient follow-up: 83% (intention-to-treat analysis). Main results The main results are in the Table. Groups did not differ for serious adverse events or death (P = 0.77). Conclusions In community-dwelling patients with moderate-to-severe Alzheimer disease, continued donepezil improved cognitive functioning and activities of daily living at 30 weeks. Memantine improved cognitive functioning at 30 weeks. 2012 American College of Physicians.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/369/CN-00903369/frame.html>

Record #80 of 370



ID: CN-00878985

AU: Amenta F

AU: Carotenuto A

AU: Fasanaro AM

AU: Rea R

AU: Traini E

TI: The ASCOMALVA trial: association between the cholinesterase inhibitor donepezil and the cholinergic precursor choline alfoscerate in Alzheimer's disease with cerebrovascular injury: interim results.

SO: Journal of the neurological sciences

YR: 2012

VL: 322

NO: 1-2

PG: 96-101

PM: PUBMED 22959283


PT: Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Alzheimer Disease [complications] [drug therapy];Cerebrovascular Disorders [complications] [drug therapy];Double-Blind Method;Follow-Up Studies;Glycerylphosphorylcholine [therapeutic use];Indans [therapeutic use];Mental Status Schedule;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1016/j.jns.2012.07.003

AB: BACKGROUND: Cholinesterase inhibitors (ChE-Is) are among the drugs more largely used for the treatment of mild-to-moderate symptoms of Alzheimer's disease (AD), but beneficial long-term effects of these compounds on the cognitive, functional, and behavioural symptoms of the disease are small and not always apparent in practice. Preclinical investigations have suggested that association between ChE-Is and the cholinergic precursor choline alphoscerate enhances cholinergic neurotransmission more effectively than single compounds alone. The ongoing clinical trial on the "Effect of association between a ChE-I and choline alphoscerate on cognitive deficits in Alzheimer's disease associated with cerebrovascular injury" (ASCOMALVA) was designed to assess if association of the ChE-I donepezil with choline alphoscerate has a more favourable clinical profile than monotherapy with donepezil alone. METHODS: ASCOMALVA is a double-blind multicentre trial that has completed the first 12 months of observation of 91 patients of the 210 planned. Patients were aged between 56 and 91 years (mean 75 ± 10 years) and were included in the protocol with a MMSE score between 15 and 24. Patients with AD diagnosed according to the DSM IV criteria suffer from ischemic brain damage documented by neuroimaging (MRI and CT scan), with a score ≥ 2 in at least one subfield of the New Rating Scale for Age-Related White Matter Changes (ARWMC). Patients were randomly allotted to an active treatment group (donepezil+choline alphoscerate) or to a reference treatment group (donepezil+placebo) and were examined after 3, 6, 9 and 12 months of treatment. RESULTS: Cognitive functions, patient's daily activities and behavioural symptoms were assessed by the Mini-Mental State Evaluation (MMSE), Alzheimer's Disease Assessment Scale Cognitive subscale (ADAS-cog), Basic Activities of Daily Living (BADL), Instrumental Activities of Daily Living (IADL) and Neuropsychiatric Inventory (NPI), of severity and of caregiver distress measures (NPI-F and NPI-D). Patients of the reference group (donepezil+placebo) showed along the course of the 12months of observation, a slight time-dependent worsening of MMSE, ADAS-cog, IADL and NPI-D scores and no changes in the BADL and NPI-F scores. Donepezil plus choline alphoscerate improved compared to donepezil alone the different items analysed except the BADL. CONCLUSIONS: The first results of the ASCOMALVA trial suggest that association of choline alphoscerate to the standard treatment with a ChE-I may represent an option to prolong beneficial effects of cholinergic therapies in AD with concomitant ischemic cerebrovascular injury.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/985/CN-00878985/frame.html>

Record #81 of 370 

ID: CN-00837280

AU: Mori E

AU: Ikeda M

AU: Kosaka K

TI: Donepezil for dementia with Lewy bodies: a randomized, placebo-controlled trial.

SO: Annals of neurology

YR: 2012

VL: 72

NO: 1

PG: 41-52

PM: PUBMED 22829268

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Cholinesterase Inhibitors [pharmacology] [therapeutic use];Cognition [drug effects];Double-Blind Method;Indans [pharmacology] [therapeutic use];Lewy Body Disease [drug therapy] [psychology];Neuropsychological Tests;Nootropic Agents [pharmacology] [therapeutic use];Piperidines [pharmacology] [therapeutic use];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1002/ana.23557

AB: OBJECTIVE: Because cholinergic deficits are prominent in dementia with Lewy bodies (DLB), we investigated the effects of a cholinesterase inhibitor, donepezil, in such patients in a randomized, double-blind, placebo-controlled exploratory phase 2 trial. METHODS: One-hundred forty patients with DLB, recruited from 48 specialty centers in Japan, were randomly assigned to receive placebo or 3, 5, or 10 mg of donepezil hydrochloride daily for 12 weeks (n = 35, 35, 33, and 37, respectively). Effects on cognitive function were assessed using the Mini-Mental State Examination (MMSE) and several domain-specific neuropsychological tests. Changes in behavior were evaluated using the Neuropsychiatric Inventory, caregiver burden using the Zarit Caregiver Burden Interview, and global function using the Clinician's Interview-Based Impression of Change-plus Caregiver Input (CIBIC-plus). Safety measures included the Unified Parkinson's Disease Rating Scale part III. RESULTS: Donepezil at 5 and 10 mg/day was significantly superior to placebo on both the MMSE (5 mg: mean difference, 3.8; 95% confidence interval [CI], 2.3-5.3; $p < 0.001$; 10 mg: mean difference, 2.4; 95% CI, 0.9-3.9; $p = 0.001$) and CIBIC-plus ($p < 0.001$ for each); 3 mg/day was significantly superior to placebo on

CIBIC-plus ($p < 0.001$), but not on the MMSE ($p = 0.017$). Significant improvements were found also in behavioral measures ($p < 0.001$) at 5 and 10 mg/day and caregiver burden ($p = 0.004$) at 10 mg/day. The safety results were consistent with the known profile of donepezil and similar among groups. INTERPRETATION: Donepezil at 5 and 10mg/day produces significant cognitive, behavioral, and global improvements that last at least 12 weeks in DLB patients, reducing caregiver burden at the highest dose. Donepezil is safe and well tolerated.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/280/CN-00837280/frame.html>

Record #82 of 370 

ID: CN-00841191

AU: Andersen F

AU: Viitanen M

AU: Halvorsen DS

AU: Straume B

AU: Wilsgaard T

AU: Engstad TA

TI: The effect of stimulation therapy and donepezil on cognitive function in Alzheimer's disease. A community based RCT with a two-by-two factorial design.

SO: BMC neurology

YR: 2012

VL: 12

PG: 59

PM: PUBMED 22813231

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [epidemiology] [therapy];Cholinesterase Inhibitors [administration & dosage];Cognition Disorders [epidemiology] [therapy];Combined Modality Therapy;Comorbidity;Double-Blind Method;Indans [administration & dosage];Norway [epidemiology];Physical Therapy Modalities [statistics & numerical data];Piperidines [administration & dosage];Prevalence;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-DEMENTIA

DOI: 10.1186/1471-2377-12-59

AB: BACKGROUND: Progressive neurodegeneration in Alzheimer's disease (AD) induces cognitive deterioration, and there is controversy regarding the optimal treatment strategy in early AD. Stimulation therapy, including physical exercise and cholinesterase inhibitors are both reported to postpone cognitive deterioration in separate studies. We aimed to study the effect of stimulation therapy and the additional effect of donepezil on cognitive function in early AD. **METHOD:** Design: A two-by-two factorial trial comprising stimulation therapy for one year compared to standard care to which a randomized double-blinded placebo controlled trial with donepezil was added. Setting: Nine rural municipalities in Northern Norway. Participants: 187 participants 65 years and older with a recent diagnosis of mild or moderate AD were included in the study of which 146 completed a one-year follow-up. **INTERVENTIONS:** In five municipalities the participants received stimulation therapy whereas participants in four received standard care. All participants were randomised double-blindly to donepezil or placebo and tested with three different cognitive tests four times during the one-year study period. Main outcome: Changes in MMSE sum score. Secondary outcome: Changes in ADAS-Cog and Clock Drawing Test. **RESULTS:** MMSE scores remained unchanged amongst AD participants receiving stimulation therapy and those receiving standard care. The results were consistent for ADAS-Cog and Clock Drawing Test. No time trend differences were found during one-year follow-up between groups receiving stimulation therapy versus standard care or between donepezil versus placebo. **CONCLUSION:** In rural AD patients non-pharmacological and pharmacological therapy did not improve outcome compared with standard care but all groups retained cognitive function during one year follow-up. Other studies are needed to confirm these results. **TRIAL REGISTRATION:** ClinicalTrials.gov (Identifier: NCT00443014). EudraCT database (no 2004-002613-37).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/191/CN-00841191/frame.html>

Record #83 of 370



ID: CN-00854138

AU: Ashare RL

AU: Ray R

AU: Lerman C

AU: Strasser AA

TI: Cognitive effects of the acetylcholinesterase inhibitor, donepezil, in healthy, non-treatment seeking smokers: a pilot feasibility study.

SO: Drug and alcohol dependence

YR: 2012

VL: 126

NO: 1-2

PG: 263-7

PM: PUBMED 22595038

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Analysis of Variance;Attention [drug effects];Cholinesterase Inhibitors [adverse effects] [pharmacology];Cognition [drug effects];Double-Blind Method;Feasibility Studies;Indans [adverse effects] [pharmacology];Medication Adherence;Neuropsychological Tests;Nootropic Agents [adverse effects] [pharmacology];Pilot Projects;Piperidines [adverse effects] [pharmacology];Psychomotor Performance [drug effects];Reaction Time [drug effects];Smoking [psychology];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-TOBACCO

DOI: 10.1016/j.drugalcdep.2012.04.019

AB: BACKGROUND: There is a need to identify medications to aid in smoking cessation. Reducing withdrawal-related cognitive deficits represents a pharmacological target for new pharmacotherapies. Endogenous acetylcholine levels, which are modulated by acetylcholinesterase inhibitors (AChEIs), play an important role in smoking behavior and cognition. This pilot feasibility study tested whether an AChEI, donepezil, enhanced cognitive performance among healthy smokers. METHODS: Eighteen non-treatment seeking daily smokers (6 female) received either donepezil (5 mg q.d) or placebo (double-blind; 2:1 allocation ratio) for 4 weeks. Smoking rate, side effects, and neurocognitive measures of working memory (Letter-N-back) and sustained attention (Penn Continuous Performance Task) were assessed weekly. RESULTS: For the working memory task, there was a significant group×load×time interaction ($p=0.03$) indicating that the donepezil group demonstrated an increase in true positives from baseline to week 4 at the highest working memory load (3-back). The placebo group showed no change in accuracy. For the sustained attention task, there was a marginal effect in the same direction for discriminability, or d' , $p=0.08$. There were no significant effects on reaction time during either task. There was also a reduction in cigarettes per day in the placebo group, but not the donepezil group. CONCLUSIONS: AChEIs, such as donepezil, may have pro-cognitive effects among healthy smokers while they continue to smoke as usual. Given the association between cognitive deficits and relapse, AChEIs should be explored as potential therapeutics for smoking cessation.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/138/CN-00854138/frame.html>

Record #84 of 370



ID: CN-00834035

AU: Sukys-Claudino L

AU: Moraes W

AU: Guilleminault C

AU: Tufik S

AU: Poyares D

TI: Beneficial effect of donepezil on obstructive sleep apnea: a double-blind, placebo-controlled clinical trial.

SO: Sleep medicine

YR: 2012

VL: 13

NO: 3

PG: 290-6

PM: PUBMED 22281004

XR: EMBASE 2012106240

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cholinesterase Inhibitors [administration & dosage] [adverse effects];Double-Blind Method;Indans [administration & dosage] [adverse effects];Oxygen [blood];Piperidines [administration & dosage] [adverse effects];Placebos;Polysomnography;Sleep Apnea, Obstructive [diagnosis] [drug therapy];Sleep Stages [drug effects];Treatment Outcome;Adult[checkword];Aged[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]


CC: SR-AIRWAYS: SR-ORAL

DOI: 10.1016/j.sleep.2011.09.014

AB: INTRODUCTION/OBJECTIVES: Previous publications have shown beneficial effects of cholinergic medication on obstructive sleep apnea (OSA) in Alzheimer's disease (AD) patients. We hypothesized that cholinergic medication could also improve OSA in non-AD patients. The present study evaluated the effects of donepezil on OSA in non-AD patients. METHODS: A

randomized, double-blind, placebo-controlled study was conducted. The final sample consisted of 21 male patients with mild to severe OSA and AHI >10 divided into two groups, a donepezil-treated group (n=11) and a placebo-treated group (n=10). The dosage was one tablet/day (5 mg) for the first two weeks and two tablets/day (10 mg) for the last two weeks. Polysomnography and sleepiness evaluations were performed at baseline and after one month of treatment. Groups were compared using two-way ANOVA for repeated measures with treatment-group and treatment-time as the main factors and time-treatment as an interaction effect. RESULTS: Considering the effect of the interaction with time-treatment, there was a significant improvement in the obstructive apnea/hypopnea index, desaturation index, percentage of time with O(2) saturation $\geq 3\%$ lower than baseline, lowest oxygen saturation, and the Epworth Sleepiness Scale (ESS) scores with donepezil treatment ($p < 0.05$). Sleep efficiency significantly decreased ($p < 0.01$). CONCLUSIONS: Donepezil treatment improved obstructive sleep apnea index, oxygen saturation, and sleepiness in parallel with a reduction in sleep efficiency. Our findings support the concept that cholinergic transmission may influence breathing regulation in OSA patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/035/CN-00834035/frame.html>

Record #85 of 370 

ID: CN-00912844

AU: Kimura T

AU: Takamatsu J

TI: Two cases of Alzheimer's disease showing deterioration of behavioral and psychological symptoms of dementia induced by switching from rivastigmine to donepezil.

SO: Neuropsychiatric disease and treatment

YR: 2012

VL: 9

NO: 1

PG: 49-53

XR: EMBASE 2013024001

PT: Journal: Article

KY: adult // aged // aggressiveness // agitation // *Alzheimer disease/di [Diagnosis] // *Alzheimer disease/dt [Drug Therapy] // article // blood examination // brain blood flow // brain cortex // case report // cingulate gyrus // clinical examination // cognitive defect //

controlled study // daily life activity // *dementia/di [Diagnosis] // *dementia/dt [Drug Therapy] // double blind procedure // drug efficacy // drug safety // drug substitution // drug tolerability // drug withdrawal // enzyme inhibition // female // herbal medicine // human // insomnia/si [Side Effect] // irritability // Japan // mental deterioration // Mini Mental State Examination // multicenter study // nuclear magnetic resonance imaging // parallel design // randomized controlled trial // scintigraphy // side effect/si [Side Effect] // treatment response // urinalysis // white matter // cholinesterase/ec [Endogenous Compound] // cholinesterase inhibitor/dt [Drug Therapy] // cholinesterase inhibitor/pd [Pharmacology] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/cm [Drug Comparison] // *donepezil/dt [Drug Therapy] // *donepezil/pd [Pharmacology] // herbaceous agent/dt [Drug Therapy] // herbaceous agent/pd [Pharmacology] // placebo // *rivastigmine/ct [Clinical Trial] // *rivastigmine/cm [Drug Comparison] // *rivastigmine/dt [Drug Therapy] // *rivastigmine/pr [Pharmaceutics] // *rivastigmine/pd [Pharmacology] // *rivastigmine/tp [Topical Drug Administration] // tandospirone/dt [Drug Therapy] // unclassified drug // yokukansan/dt [Drug Therapy] // yokukansan/pd [Pharmacology]

DOI: 10.2147/NDT.S37688

AB: Rivastigmine, galantamine, and memantine, in addition to donepezil, which has been on the market over 10 years, have been available for the treatment of Alzheimer's disease (AD) since 2011 in Japan, leading a new stage in the medical treatment of AD. We studied two AD patients showing sudden deterioration of behavioral and psychological symptoms of dementia (BPSD) associated with switching from rivastigmine to donepezil after the clinical trial of rivastigmine. In the patients, rivastigmine seemed to be more beneficial than donepezil for the control of BPSD. Although It was not obvious whether their different responses to the two cholinesterase inhibitors were due to the different pharmacological profiles, i.e., the presence of inhibition of butyrylcholinesterase in rivastigmine, a particular cholinesterase inhibitor might be more effective in particular AD cases. Further investigations are needed to confirm the difference, and to identify the measures for selecting the most appropriate medication for each AD patient. 2013 Kimura and Takamatsu, publisher and licensee Dove Medical Press Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/844/CN-00912844/frame.html>

Record #86 of 370



ID: CN-00843210

AU: Engedal K

AU: Davis B

AU: Richarz U

AU: Han J

AU: Schäuble B

AU: Andreasen N

TI: Two galantamine titration regimens in patients switched from donepezil.

SO: Acta neurologica Scandinavica

YR: 2012

VL: 126

NO: 1

PG: 37-44

PM: PUBMED 21992111

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Cholinesterase Inhibitors [administration & dosage] [therapeutic use];Dose-Response Relationship, Drug;Drug Administration Schedule;Galantamine [administration & dosage] [therapeutic use];Indans [therapeutic use];Neuropsychological Tests;Piperidines [therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1111/j.1600-0404.2011.01594.x

AB: OBJECTIVES: In addition to inhibiting acetylcholinesterase, galantamine has allosteric-modulating activity at nicotinic receptors. This may make galantamine an attractive option for patients starting treatment for Alzheimer's disease (AD), but also for those who have not benefited from their current therapy. This study explored outcomes in subjects with AD transitioning from donepezil because of insufficient tolerability or efficacy. MATERIALS AND METHODS: Subjects previously receiving donepezil for mild-to-moderate AD were enrolled in a 12-week randomized, open-label study. After screening and a 7-day washout, subjects were randomly allocated to galantamine fast (8 mg/week increments) or slow (8 mg/4 week) titration to 16-24 mg. Efficacy outcomes included the Alzheimer's Disease Assessment Scale - cognitive subscale (ADAS-cog/11), Mini-Mental State Examination (MMSE), Clinician's Interview-Based Impression of Change - Plus Caregiver's Input (CIBIC-plus) and Alzheimer's Disease Cooperative Study - Activities of Daily Living Inventory (ADCS-ADL). RESULTS: Eighty-six of 89 patients (fast titration, n = 44; slow titration, n = 45) completed the study. At week 12, ADAS-cog/11 score improved from screening by 2.6 and 0.6 in the fast- and slow-titration arms, respectively (overall, -1.6; P = 0.002). MMSE scores improved slightly in both arms (overall, +0.9; P = 0.002). Two-thirds of patients had improvement or no change on the CIBIC-plus at week 12. ADCS-ADL scores did not change significantly from screening in either treatment arm. Galantamine was generally well tolerated; nausea (5.6%) and bradycardia

(4.5%) were the most commonly reported adverse events. CONCLUSIONS: Patients in whom donepezil is ineffective or poorly tolerated may benefit from a switch to galantamine.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/210/CN-00843210/frame.html>

Record #87 of 370



ID: CN-00843318

AU: Lenz RA

AU: Baker JD

AU: Locke C

AU: Rueter LE

AU: Mohler EG

AU: Wesnes K

AU: Abi-Saab W

AU: Saltarelli MD

TI: The scopolamine model as a pharmacodynamic marker in early drug development.

SO: Psychopharmacology

YR: 2012

VL: 220

NO: 1

PG: 97-107

PM: PUBMED 21901320

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cognition Disorders [drug therapy] [physiopathology]; Disease Models, Animal; Dose-Response Relationship, Drug; Drug Design; Indans [administration & dosage] [pharmacology]; Maze Learning [drug effects]; Memory [drug effects]; Muscarinic Antagonists [administration & dosage] [toxicity]; Nootropic Agents [administration & dosage] [pharmacology]; Piperidines [administration & dosage] [pharmacology]; Rats; Rats, Long-Evans; Scopolamine Hydrobromide [administration & dosage] [toxicity]; Single-Blind Method; Species Specificity; Time

Factors;Adult[checkword];Animals[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]


DOI: 10.1007/s00213-011-2456-4

AB: RATIONALE: Drug development is a high-risk and high failure enterprise, and studies that provide an early read on the pharmacodynamic activity of novel compounds could save time and money, increasing the efficiency of the drug development process. OBJECTIVE: Preclinical and clinical experiments were designed to examine the utility of the scopolamine-induced cognitive impairment model in predicting pharmacodynamic signals of putatively procognitive compounds, utilizing the acetylcholinesterase inhibitor donepezil for illustration.

METHODS/RESULTS: In normal healthy rats, scopolamine (0.3 mg/kg) significantly impaired performance on the two-platform water maze and on the T-maze. The deficits in water maze performance were reversed by donepezil at 0.5 and 1.0 mg/kg. There was a trend towards reversal of scopolamine-induced deficits in performance on the T-maze with 1.0 mg/kg donepezil. In normal healthy humans, scopolamine (0.3 and 0.5 mg) reliably impaired performance on the Cognitive Drug Research test battery composite scores (power of attention, continuity of attention, quality of working memory, quality of episodic secondary memory, and speed of memory) in a dose- and time-dependent manner. Donepezil (10 mg) significantly attenuated the scopolamine-induced impairment in cognition on power of attention, continuity of attention, quality of working memory, and speed of memory.

CONCLUSIONS: These findings suggest that reversal of scopolamine-induced cognitive impairment is a viable model for predicting pharmacodynamic signals of procognitive compounds in both animals and humans. The utility of the scopolamine-induced cognitive impairment model is discussed and illustrated at various decision points in drug development, with a focus on Go/No Go decisions.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/318/CN-00843318/frame.html>

Record #88 of 370 

ID: CN-00851401

AU: Moon KT

TI: Is donepezil an effective treatment for depression in older persons?

SO: American family physician

YR: 2012

VL: 85

NO: 2

PG: 5

CC: SR-DEPRESSN

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/401/CN-00851401/frame.html>

Record #89 of 370



ID: CN-00896948

AU: Sweetlove M

TI: Phase III CONCERT trial of latrepirdine: Negative results.

SO: Pharmaceutical medicine

YR: 2012

VL: 26

NO: 2

PG: 113-5

XR: EMBASE 2012165417

PT: Journal: Article

KY: adjuvant therapy // adult // *Alzheimer disease/dt [Drug Therapy] // Alzheimer Disease Assessment Scale // Alzheimer disease cooperative study activities of daily living inventory // article // controlled study // disease severity // double blind procedure // drug efficacy // drug safety // drug tolerability // female // human // major clinical study // male // monotherapy // multicenter study // named inventories, questionnaires and rating scales // outcome assessment // phase 3 clinical trial // priority journal // randomized controlled trial // treatment duration // *dimebon/ct [Clinical Trial] // *dimebon/cb [Drug Combination] // *dimebon/dt [Drug Therapy] // *dimebon/po [Oral Drug Administration] // donepezil/cb [Drug Combination] // donepezil/dt [Drug Therapy] // placebo

DOI: 10.2165/11631260-000000000-00000

AB: CONCERT: a Phase III multicentre randomized, placebo-controlled, double-blind 12-month safety and efficacy study evaluating dimebon in patients with mild-to-moderate Alzheimer's disease on donepezil. This trial investigated the efficacy and tolerability of adjunctive therapy with latrepirdine at 15 or 60mg/day in patients with mild-to-moderate Alzheimer's disease receiving stable treatment with donepezil. The co-primary outcomes were Alzheimer's Disease Assessment Scale-cognitive subscale or Alzheimer's Disease Cooperative Study - Activities of

Daily Living Inventory scores. Trial results showed that latrepirdine failed to improve either of the primary endpoints compared with placebo, leading to discontinuation of latrepirdine development for all indications. 2012 Adis Data Information BV. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/948/CN-00896948/frame.html>

Record #90 of 370



ID: CN-00863335

AU: Zhang Z

AU: Yu L

AU: Gaudig M

AU: Schauble B

AU: Richarz U

TI: Galantamine versus donepezil in Chinese patients with Alzheimer's disease: results from a randomized, double-blind study

SO: Neuropsychiatric disease and treatment

YR: 2012

VL: 8

PG: ArtID 571-577

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/335/CN-00863335/frame.html>

Record #91 of 370



ID: CN-00858752

AU: Howard R

AU: McShane R

AU: Lindesay J

AU: Ritchie C

AU: Baldwin A

AU: Barber R

TI: Donepezil and memantine for moderate-to-severe Alzheimer's disease

SO: New England journal of medicine

YR: 2012

VL: 366

NO: 10

PG: 893-903

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/752/CN-00858752/frame.html>

Record #92 of 370



ID: CN-00883327

AU: Fadaei F

TI: A double-blind, placebo controlled cross-over trial of adjunction of donepezil to atypical antipsychotics for cognitive impairment in schizophrenia

SO: Journal of neurology

YR: 2012

VL: Conference: 22nd Meeting of the European Neurological Society Prague Czech Republic.
Conference Start: 20120609 Conference End: 20120612. Conference Publication:

NO: var.pagings

PG: S131-S132

XR: EMBASE 71230042

CC: SR-DEMENTIA

DOI: 10.1007/s00415-012-6524-4

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/327/CN-00883327/frame.html>

Record #93 of 370



ID: CN-00865297

AU: Sabbagh M

AU: Cummings J

AU: Christensen D

AU: Doody R

AU: Farlow M

AU: MacKell J

TI: Evaluating the cognitive effects of donepezil 23 MG/D in moderate and severe Alzheimer's disease: A patient subgroup analysis

SO: Journal of nutrition, health & aging

YR: 2012

VL: Conference: 5th Conference Clinical Trials on Alzheimer's Disease Monte Carlo Monaco.
Conference Start: 20121029 Conference End: 20121031. Conference Publication:

NO: var.pagings

PG: 837

XR: EMBASE 70988261

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/297/CN-00865297/frame.html>

Record #94 of 370

ID: CN-00865296

AU: Ferris S

AU: Cummings J

AU: Christensen D

AU: Doody R

AU: Farlow M

AU: Sabbagh M

TI: Donepezil 23 MG/D for moderate to severe Alzheimer's disease: Assessing subdomains of the severe impairment battery

SO: Journal of nutrition, health & aging

YR: 2012

VL: Conference: 5th Conference Clinical Trials on Alzheimer's Disease Monte Carlo Monaco.
Conference Start: 20121029 Conference End: 20121031. Conference Publication:

NO: var.pagings

PG: 837-8

XR: EMBASE 70988262

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/296/CN-00865296/frame.html>

Record #95 of 370



ID: CN-00865295

AU: Masterman D

AU: Awipi T

AU: Ashford E

AU: Nave S

AU: Yoo K

AU: Vellas B

TI: A nicotinic-alpha-7 partial agonist as adjunctive therapy to stable donepezil

SO: Journal of nutrition, health & aging

YR: 2012

VL: Conference: 5th Conference Clinical Trials on Alzheimer's Disease Monte Carlo Monaco.
Conference Start: 20121029 Conference End: 20121031. Conference Publication:


NO: var.pagings

PG: 838-9

XR: EMBASE 70988264

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/295/CN-00865295/frame.html>

Record #96 of 370 

ID: CN-00863185

AU: Christensen DD

TI: Higher-dose (23 mg/day) donepezil formulation for the treatment of patients with moderate-to-severe Alzheimer's disease. [Review]

SO: Postgraduate medicine

YR: 2012

VL: 124

NO: 6

PG: 110-6

PM: PUBMED 23322144

XR: EMBASE 2013264615

PT: Journal Article; Research Support, Non-U.S. Gov't; Review

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/185/CN-00863185/frame.html>

Record #97 of 370



ID: CN-00874411

AU: Woreta F

AU: Munoz B

AU: Gower E

AU: Alemayehu W

AU: West SK

TI: Three-year outcomes of the surgery for trichiasis, antibiotics to prevent recurrence trial.

SO: Archives of ophthalmology

YR: 2012

VL: 130

NO: 4

PG: 427-31

PM: PUBMED 22159169

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Administration, Oral;Administration, Topical;Anti-Bacterial Agents [administration & dosage];Azithromycin [administration & dosage];Endemic Diseases;Ethiopia [epidemiology];Follow-Up Studies;Incidence;Ophthalmologic Surgical Procedures;Recurrence [prevention & control];Single-Blind Method;Tetracycline [administration & dosage];Treatment Outcome;Trichiasis [drug therapy] [epidemiology] [prevention & control] [surgery];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1001/archophthalmol.2011.374

AB: OBJECTIVE: To determine whether treatment with oral azithromycin compared with topical tetracycline reduces the recurrence of trichiasis for up to 3 years following surgery for trichiasis. METHODS: The Surgery for Trichiasis, Antibiotics to Prevent Recurrence (STAR) trial is a randomized, single-masked, clinical trial conducted in southern Ethiopia, a region where trachoma is hyperendemic. A total of 1452 patients who underwent trichiasis surgery were randomly assigned at a 2:1 ratio to either a single dose of oral azithromycin (1 g) or topical tetracycline (twice per day for 6 weeks) following surgery. MAIN OUTCOME MEASURES: Recurrence of trichiasis within 3 years following surgery. RESULTS: The rate of recurrence was 10% in the azithromycin group and 13% in the tetracycline group. The azithromycin group had a 22% reduction in recurrence of trichiasis 3 years after surgery compared with the tetracycline group ($P = .13$). Severity of entropion at baseline was the most significant predictor of

recurrence of trichiasis at 3 years. CONCLUSION: Trichiasis recurrence rates in the STAR trial remained low for up to 3 years following surgery. The protective effect of a single dose of azithromycin was less than at 1 year and, although not statistically significant, was still suggestive up to 3 years following trichiasis surgery. APPLICATION TO CLINICAL PRACTICE: A single dose of azithromycin after surgery remains an integral component of the World Health Organization's strategy for the elimination of trachoma by the year 2020.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/411/CN-00874411/frame.html>

Record #98 of 370



ID: CN-00898836

AU: Cook C

AU: Carrara H

AU: Myer L

TI: Phaco-emulsification versus manual small-incision cataract surgery in South Africa.

SO: South African Medical Journal

YR: 2012

VL: 102

NO: 6

PG: 537-540

XR: EMBASE 2012706576

KY: adult // aged // article // astigmatism // *cataract extraction // controlled study // cornea edema // eye refraction // female // follow up // human // intermethod comparison // lens capsule rupture // major clinical study // male // peroperative complication // *phaco emulsification cataract extraction // postoperative complication // prospective study // randomized controlled trial // senile cataract/su [Surgery] // *small incision cataract extraction // South Africa // treatment outcome // visual acuity // antibiotic agent/cb [Drug Combination] // antibiotic agent/tp [Topical Drug Administration] // steroid/cb [Drug Combination] // steroid/tp [Topical Drug Administration]

AB: Objectives. To compare the results of phaco-emulsification cataract surgery and manual small-incision cataract surgery. Methods. Consecutive patients aged >50 years undergoing surgery for age-related cataract were recruited into a randomised prospective clinical trial. Randomisation was done using opaque sequentially numbered envelopes opened by the

surgeon immediately prior to surgery. The patients were seen after 1 day, 2 weeks, and 8 weeks. Outcome measures. The primary outcome measure was the uncorrected visual acuity at week 8. The secondary outcome measures were the uncorrected visual acuity on day 1, the best corrected visual acuity at week 8, the refraction at week 8, and the intra- and postoperative complications. Results. One hundred patients were recruited into each arm of the study. There was no difference in the incidence of intraocular complications ($p=0.19$). There was no difference in the day 1 visual acuities ($p=0.28$). However, both the uncorrected and the corrected week 8 visual acuities were better in the eyes that had phaco-emulsification ($p=0.02$ and $p=0.03$), and there was less astigmatism ($p=0.001$) at week 8 in the eyes that had phacoemulsification. Conclusions. While manual small-incision surgery has been recommended as an acceptable alternative to phaco-emulsification in middle- and low-income countries, we have found that the results of phaco-emulsification are better. Where appropriate, consideration should be given to encouraging a transition to phaco-emulsification in our Vision 2020 programmes in Africa.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/836/CN-00898836/frame.html>

Record #99 of 370



ID: CN-00840443

AU: McLaren DG

AU: Sreenivasan A

AU: Diamond EL

AU: Mitchell MB

AU: Dijk KR

AU: Deluca AN

AU: O'Brien JL

AU: Rentz DM

AU: Sperling RA

AU: Atri A

TI: Tracking cognitive change over 24 weeks with longitudinal functional magnetic resonance imaging in Alzheimer's disease.

SO: Neuro-degenerative diseases

YR: 2012

VL: 9

NO: 4

PG: 176-86

PM: PUBMED 22456451

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, Non-P.H.S.

KY: Alzheimer Disease [drug therapy] [pathology] [physiopathology]; Brain Mapping; Cognition [physiology]; Dopamine Agents [therapeutic use]; Indans [therapeutic use]; Longitudinal Studies; Magnetic Resonance Imaging; Memantine [therapeutic use]; Neuropsychological Tests; Nootropic Agents [therapeutic use]; Oxygen [blood]; Piperidines [therapeutic use]; Regression Analysis; Aged[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

DOI: 10.1159/000335876

AB: BACKGROUND: Previous studies have revealed that functional magnetic resonance imaging (fMRI) blood oxygen level-dependent (BOLD) signal in specific brain regions correlates with cross-sectional performance on standardized clinical trial measures in Alzheimer's disease (AD); however, the relationship between longitudinal change in fMRI-BOLD signal and neuropsychological performance remains unknown. OBJECTIVE: To identify changes in regional fMRI-BOLD activity that tracks change in neuropsychological performance in mild AD dementia over 6 months. METHODS: Twenty-four subjects (mean age 71.6) with mild AD dementia (mean Mini Mental State Examination 21.7, Global Clinical Dementia Rating 1.0) on stable donepezil dosing participated in two task-related fMRI sessions consisting of a face-name paired associative encoding memory paradigm 24 weeks apart during a randomized placebo-controlled pharmacofMRI drug study. Regression analysis was used to identify regions where the change in fMRI activity for Novel > Repeated stimulus contrast was associated with the change scores on postscan memory tests and the Free and Cued Selective Reminding Test (FCSRT). RESULTS: Correlations between changes in postscan memory accuracy and changes in fMRI activity were observed in regions including the angular gyrus, parahippocampal gyrus, inferior frontal gyrus and cerebellum. Correlations between changes in FCSRT-free recall and changes in fMRI were observed in regions including the inferior parietal lobule, precuneus, hippocampus and parahippocampal gyrus. CONCLUSION: Changes in encoding-related fMRI activity in regions implicated in mnemonic networks correlated with changes in psychometric measures of episodic memory retrieval performed outside the scanner. These exploratory results support the potential of fMRI activity to track cognitive change and detect signals of short-term pharmacologic effect in early-phase AD studies.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/443/CN-00840443/frame.html>

Record #100 of 370



ID: CN-00903539

AU: Arns da cunha C

AU: Stevens M

AU: Buelens A

AU: Vanveggel S

AU: Boven K

AU: Abusamra L

AU: Cahn P

AU: Laplume HE

AU: Cassetti I

AU: Ceriotto M

AU: Martins MD

AU: Krolewiecki A

AU: Amarilis Lugo L

AU: Bolan R

AU: Bush L

AU: Corales R

AU: Crane L

AU: Vente J

AU: Fischl M

AU: Gathe J

AU: Greenberg R

AU: Henry K

AU: Jayaweera D

AU: Kumar P
AU: Lalezari J
AU: Leider J
AU: Lubelchek R
AU: Martorell C
AU: Mounzer K
AU: Cohen C
AU: Olivet H
AU: Ortiz R
AU: Rhame F
AU: Roberts A
AU: Ruane P
AU: Scribner A
AU: Segal-Maurer S
AU: Short W
AU: Sloan L
AU: Wilkin T
AU: Wohlfeiler M
AU: Yangco B
AU: Bloch M
AU: Gold J
AU: Hoy J
AU: Martinez P
AU: Baker D
AU: Finlayson R
AU: Roth N
AU: Rieger A

AU: Vetter N

AU: Zangerle R

AU: Cunha CA

AU: Grinsztejn B

AU: Madruga JV

AU: Pilotto JH

AU: Sampaio D

AU: Gonzalez CR

AU: Lima MP

AU: Rangel F

AU: Timerman A

AU: Junod P

AU: Kilby D

AU: Rachlis A

AU: Walmsley S

AU: Boissonnault M

AU: Brunetta J

AU: Wet J

AU: Gill J

AU: Kasper K

AU: Macleod J

AU: Gerstoft J

AU: Mathiesen L

AU: Pedersen C

AU: Cotte L

AU: Girard P-M

AU: Molina JM

AU: Raffi F

AU: Vittecoq D

AU: Yazdanpanah Y

AU: Yeni P

AU: Boue F

AU: Katlama C

AU: Reynes J

AU: Fisher M

AU: Nelson M

AU: Orkin C

AU: Taylor S

AU: Johnson M

AU: Wilkins E

AU: Williams IG

AU: Winston A

AU: Lazzarin A

AU: Narciso P

AU: Orani A

AU: Rusconi S

AU: Antinori A

AU: Carosi G

AU: Mazzotta F

AU: Amaya G

AU: Reyes-Teran G

AU: Andrade-Villanueva J

AU: Sierra Madero JG

AU: Rijnders B

AU: Santana J
AU: Zorrilla C
AU: Antunes F
AU: Branco T
AU: Sarmento R
AU: Castro E
AU: Eugenio T
AU: Mansinho K
AU: Marques R
AU: Duiculescu D
AU: Negrutiu L
AU: Prisacariu L
AU: Kulagin V
AU: Voronin E
AU: Yakovlev A
AU: Dushkina N
AU: Pronin A
AU: Tsibakova O
AU: Vinogradova E
AU: Baraldi E
AU: David N
AU: Ebrahim O
AU: Krantz E
AU: Latiff GH
AU: Spencer D
AU: Wood R
AU: Botes M

AU: Conradie F
AU: Fourie J
AU: Mohapi L
AU: Petit D
AU: Steyn D
AU: Arribas JR
AU: Portilla Sogorb J
AU: Ribera E
AU: Santos Gil I
AU: Clotet B
AU: Gutierrez F
AU: Podzamczar D
AU: Soriano V
AU: Westling K
AU: Chetchotisakd P
AU: Sirisanthana T
AU: Sungkanuparph S
AU: Vibhagool A
AU: Ruxrungtham K
AU: Techasathit W
AU: Hung C-C
AU: Lee H-C
AU: Lin H-H
AU: Wong WW
AU: Albrecht H
AU: Bellos N
AU: Berger D

AU: Brinson C
AU: Casanas B
AU: Elion R
AU: Feinberg J
AU: File T
AU: Flamm J
AU: Hicks C
AU: Hodder S
AU: Hsiao C-B
AU: Kadlecik P
AU: Khanlou H
AU: Kinder C
AU: Liporace R
AU: Mayer C
AU: Mildvan D
AU: Mills A
AU: Myers RA
AU: Nadeem I
AU: Osiyemi O
AU: Para M
AU: Pierone G
AU: Rashbaum B
AU: Rodriguez J
AU: Saag M
AU: Sampson J
AU: Samuel R
AU: Sension M

AU: Shalit P
AU: Tebas P
AU: Towner W
AU: Wilkin A
AU: Eron J
AU: Wohl D
AU: Colebunders R
AU: Clumeck N
AU: Goffard J-C
AU: Wanseele F
AU: Wijngaerden E
AU: Ballesteros J
AU: Northland R
AU: Perez C
AU: Hongzhou L
AU: Li T
AU: Cai W
AU: Wu H
AU: Li X
AU: Herrera G
AU: Arasteh K
AU: Esser S
AU: Fatkenheuer G
AU: Lutz T
AU: Schmidt R
AU: Schuster D
AU: Stellbrink H-J

AU: Kumarasamy N

AU: Patil P

AU: Canton Martinez A

AU: Rodriguez-French A

AU: Sosa N

TI: Efficacy and safety of rilpivirine in treatment-naive, HIV-1-infected patients with hepatitis B virus/hepatitis C virus coinfection enrolled in the phase III randomized, double-blind ECHO and THRIVE trials.

SO: Journal of antimicrobial chemotherapy

YR: 2012

VL: 67

NO: 8

PG: 2020-8

XR: EMBASE 2012455263

PT: Journal: Article

KY: acute hepatitis/si [Side Effect] // adult // aged // alanine aminotransferase blood level // *antiviral therapy // article // aspartate aminotransferase blood level // bilirubin blood level // cholelithiasis/si [Side Effect] // controlled study // cytolytic hepatitis/si [Side Effect] // double blind procedure // drug efficacy // drug safety // drug tolerability // drug withdrawal // fatty liver/si [Side Effect] // female // hepatitis/si [Side Effect] // *hepatitis B // *hepatitis C // hepatomegaly/si [Side Effect] // human // *Human immunodeficiency virus 1 infection/dt [Drug Therapy] // *Human immunodeficiency virus infected patient // hyperbilirubinemia/si [Side Effect] // hypertransaminasemia/si [Side Effect] // liver function // liver function test // major clinical study // male // *mixed infection/si [Side Effect] // randomized controlled trial // seroconversion // side effect/si [Side Effect] // therapy effect // treatment response // virus load // alanine aminotransferase/ec [Endogenous Compound] // aspartate aminotransferase/ec [Endogenous Compound] // bilirubin/ec [Endogenous Compound] // efavirenz/ae [Adverse Drug Reaction] // efavirenz/ct [Clinical Trial] // efavirenz/cm [Drug Comparison] // efavirenz/dt [Drug Therapy] // hepatitis B surface antigen/ec [Endogenous Compound] // hepatitis C antibody/ec [Endogenous Compound] // *rilpivirine/ae [Adverse Drug Reaction] // *rilpivirine/ct [Clinical Trial] // *rilpivirine/cm [Drug Comparison] // *rilpivirine/dt [Drug Therapy]

DOI: 10.1093/jac/dks130

AB: Objectives: The efficacy and hepatic safety of the non-nucleoside reverse transcriptase inhibitors rilpivirine (TMC278) and efavirenz were compared in treatment-naive, HIV-infected

adults with concurrent hepatitis B virus (HBV) and/or hepatitis C virus (HCV) infection in the pooled week 48 analysis of the Phase III, double-blind, randomized ECHO (NCT00540449) and THRIVE (NCT00543725) trials. Methods: Patients received 25 mg of rilpivirine once daily or 600 mg of efavirenz once daily, plus two nucleoside/nucleotide reverse transcriptase inhibitors. At screening, patients had alanine aminotransferase/aspartate aminotransferase levels <5x the upper limit of normal. HBV and HCV status was determined at baseline by HBV surface antigen, HCV antibody and HCV RNA testing. Results: HBV/HCV coinfection status was known for 670 patients in the rilpivirine group and 665 in the efavirenz group. At baseline, 49 rilpivirine and 63 efavirenz patients [112/1335 (8.4%)] were coinfectd with either HBV [55/1357 (4.1%)] or HCV [57/1333 (4.3%)]. The safety analysis included all available data, including beyond week 48. Eight patients seroconverted during the study (rilpivirine: five; efavirenz: three). A higher proportion of patients achieved viral load <50 copies/mL (intent to treat, time to loss of virological response) in the subgroup without HBV/HCV coinfection (rilpivirine: 85.0%; efavirenz: 82.6%) than in the coinfectd subgroup (rilpivirine: 73.5%; efavirenz: 79.4%) (rilpivirine, P = 0.04 and efavirenz, P = 0.49, Fisher's exact test). The incidence of hepatic adverse events (AEs) was low in both groups in the overall population (rilpivirine: 5.5% versus efavirenz: 6.6%) and was higher in HBV/HCV-coinfectd patients than in those not coinfectd (26.7% versus 4.1%, respectively). Conclusions: Hepatic AEs were more common and response rates lower in HBV/HCV-coinfectd patients treated with rilpivirine or efavirenz than in those who were not coinfectd. The Author 2012. Published by Oxford University Press on behalf of the British Society for Antimicrobial Chemotherapy. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/539/CN-00903539/frame.html>

Record #101 of 370



ID: CN-00917517

AU: Pegolo E

AU: Machin P

AU: Riosa F

AU: Bassini A

AU: Deroma L

AU: Loreto C

TI: Hormone receptor and human epidermal growth factor receptor 2 status evaluation on thinprep specimens from breast Carcinoma: Correlation with histologic sections determination.

SO: Cancer cytopathology

YR: 2012

VL: 120

NO: 3

PG: 196-205

XR: EMBASE 2013008542

PT: Journal: Article

KY: adult // aged // article // *breast carcinoma/di [Diagnosis] // controlled clinical trial // controlled study // cytology // embedding // fine needle aspiration biopsy // fluorescence in situ hybridization // formalin fixed paraffin embedded // human // human cell // human tissue // *immunocytochemistry // *immunohistochemistry // major clinical study // primary tumor/di [Diagnosis] // priority journal // prospective study // tissue fixation // tissue section // *epidermal growth factor receptor 2/ec [Endogenous Compound] // *estrogen receptor/ec [Endogenous Compound] // *progesterone receptor/ec [Endogenous Compound]

DOI: 10.1002/cncy.20206


AB: BACKGROUND: Fine-needle aspiration cytology (FNAC) is a well-accepted procedure for the diagnosis and biological characterization of breast carcinoma. Estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) status have a strong prognostic and predictive value in invasive breast carcinoma (IBC). Thin- Prep (TP) cytology, which uses an alcohol-based fixative, is increasingly being used for immunocytochemistry. In this study, the authors compared the immunocytochemical evaluation of hormone receptors (HR) and HER2 on TP-processed FNAC with the immunohistochemical analysis performed on the corresponding formalin-fixed paraffin-embedded (FFPE) breast tumor specimens, which are considered the gold standard.

METHODS: FNACs were performed on 116 primary IBCs at the time of diagnosis and subjected to immunocytochemical evaluation of HR and HER2 using the TP method. The same markers were immunohistochemically evaluated on the corresponding FFPE tissue specimens. HER2 fluorescent in situ hybridization analysis was performed only on the equivocal immunohistochemical results.

RESULTS: The HR results of the TP cytology specimens showed a very good agreement with those of the corresponding FFPE tissue samples (Cohen kappa test = 0.92; concordance rate = 98%) for estrogen receptor, and a good agreement (kappa = 0.76; concordance rate = 90.9%) for progesterone receptor. A perfect agreement (kappa = 1) was observed between TP and FFPE tissue samples in evaluating HER2 status.

CONCLUSIONS: Alcohol-based fixation seems not to affect the immunocytochemical evaluation of HR and HER2. Considering the high levels of agreement between the evaluation of HR and HER2, on both cytology specimens and on the corresponding FFPE tissue samples, the authors concluded that the TP technique can be routinely used for the biological characterization of IBC. 2011 American Cancer Society.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/517/CN-00917517/frame.html>

Record #102 of 370 

ID: CN-00881349

AU: Brundage M

AU: Gropp M

AU: Mefti F

AU: Mann K

AU: Lund B

AU: Gebski V

AU: Wolfram G

AU: Reed N

AU: Pignata S

AU: Ferrero A

AU: Brown C

AU: Eisenhower E

AU: Pujade-Lauraine E

TI: Health-related quality of life in recurrent platinum-sensitive ovarian cancer--results from the CALYPSO trial.

SO: Annals of oncology

YR: 2012

VL: 23

NO: 8

PG: 2020-7

PM: PUBMED 22291207

PT: Clinical Trial; Clinical Trial, Phase III; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Antineoplastic Combined Chemotherapy Protocols [adverse effects] [therapeutic use]; Carboplatin [administration & dosage] [adverse effects]; Doxorubicin [administration &

dosage] [adverse effects] [analogs & derivatives];Medication Adherence;Neoplasm Recurrence, Local [drug therapy];Ovarian Neoplasms [drug therapy];Paclitaxel [administration & dosage] [adverse effects];Polyethylene Glycols [administration & dosage] [adverse effects];Quality of Life;Female[checkword];Humans[checkword]

DOI: 10.1093/annonc/mdr583

AB: BACKGROUND: In the CALYPSO trial, carboplatin-pegylated liposomal doxorubicin (CD) demonstrated superior therapeutic index versus carboplatin-paclitaxel (CP) in patients with recurrent ovarian cancer. This paper reports the health-related quality of life (HRQoL) findings. MATERIALS AND METHODS: HRQoL was measured with the EORTC QoL-QC30 questionnaire and OV28 ovarian cancer module. Mean change scores from baseline in HRQoL subscales (five functional scales and global health status) in each arm and the proportion of patients improved or worsened were calculated every 3 months until 12 months. RESULTS: Compliance was 90% at baseline and 76%, 64%, 57% at 3, 6, and 9 months, respectively. Baseline HRQoL showed already impaired global scores (mean 62/100) and considerable symptom burden (90% of patients reporting nonzero scores). Global QoL and abdominal symptom scores improved over time in both arms; at 6 months, 36% of patients met criteria for improved symptoms. Treatment with CD resulted in less peripheral neuropathy (9.8 versus 24.2), fewer other chemotherapy side-effects (9.5 versus 16.2), and less impact on body image (3.8 versus 10.4) versus CP (all $P < 0.02$) at 6 months. CONCLUSIONS: These patient-reported outcomes confirm the overall lower toxicity of CD versus CP. The improved disease-related outcomes achieved with CD were not at the expense of QoL.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/349/CN-00881349/frame.html>

Record #103 of 370 

ID: CN-00913423

AU: Geuns R-J

AU: Tamburino C

AU: Fajadet J

AU: Vrolix M

AU: Witzenbichler B

AU: Eeckhout E

AU: Spaulding C

AU: Reczuch K

AU: Manna A

AU: Spaargaren R

AU: Garcia-Garcia HM

AU: Regar E

AU: Capodanno D

AU: Langenhove G

AU: Verheye S

TI: Self-expanding versus balloon-expandable stents in acute myocardial infarction: Results from the APPOSITION II Study: Self-expanding stents in ST-segment elevation myocardial infarction.

SO: JACC: Cardiovascular Interventions

YR: 2012

VL: 5

NO: 12

PG: 1209-1219

XR: EMBASE 2012740073

KY: adult // angiography // article // *balloon expandable stent // bypass surgery // comparative effectiveness // complication/co [Complication] // controlled study // coronary artery bypass graft // diabetes mellitus // female // heart death // human // hyperlipidemia // hypertension // major clinical study // male // multicenter study // optical coherence tomography // outcome assessment // percutaneous coronary intervention // priority journal // randomized controlled trial // recurrent disease // revascularization // *self expanding stent // *ST segment elevation myocardial infarction/th [Therapy] // *stent // stent malapposition/co [Complication] // stent thrombosis/co [Complication] // thrombus aspiration

DOI: <http://dx.doi.org/10.1016/j.jcin.2012.08.016>

AB: Objectives: This study sought to investigate whether self-expanding stents are more effective than balloon-expandable stents for reducing stent malapposition at 3 days after implantation in patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention. Background: Acute myocardial infarction is associated with vasoconstriction and large thrombus burden. Resolution of vasoconstriction and thrombus load during the first hours to days after primary percutaneous coronary intervention may lead to stent undersizing and malapposition, which may subsequently lead to stent thrombosis or restenosis. In addition, aggressive stent deployment may cause distal embolization. Methods: Eighty patients with ST-segment elevation myocardial infarction undergoing primary percutaneous coronary intervention were randomized to receive a self-

expanding stent (STENTYS, STENTYS SA, Paris, France) (n = 43) or a balloon-expandable stent (VISION, Abbott Vascular, Santa Clara, California; or Driver, Medtronic, Minneapolis, Minnesota) (n = 37) at 9 European centers. The primary endpoint was the proportion of stent strut malapposition at 3 days after implantation measured by optical coherence tomography. Secondary endpoints included major adverse cardiac events (cardiac death, recurrent myocardial infarction, emergent bypass surgery, or clinically driven target lesion revascularization). Results: At 3 days after implantation, on a per-strut basis, a lower rate of malapposed stent struts was observed by optical coherence tomography in the self-expanding stent group than in the balloon-expandable group (0.58% vs. 5.46%, $p < 0.001$). On a per-patient basis, none of the patients in the self-expanding stent group versus 28% in the balloon-expandable group presented $\geq 5\%$ malapposed struts ($p < 0.001$). At 6 months, major adverse cardiac events were 2.3% versus 0% in the self-expanding and balloon-expandable groups, respectively ($p = \text{NS}$). Conclusions: Strut malapposition at 3 days is significantly lower in ST-segment elevation myocardial infarction patients allocated to self-expanding stents when than in those allocated to balloon-expandable stents. The impact of this difference on clinical outcome and the risk of late stent thrombosis need to be evaluated further. (Randomized Comparison Between the STENTYS Self-expanding Coronary Stent and a Balloon-expandable Stent in Acute Myocardial Infarction [APPOSITION II]; NCT01008085) 2012 American College of Cardiology Foundation.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/423/CN-00913423/frame.html>

Record #104 of 370



ID: CN-00902143

AU: Brady CJ

AU: Villanti AC

AU: Gandhi M

AU: Friedman DS

AU: Keay L

TI: Visual function after correction of distance refractive error with ready-made and custom spectacles: A randomized clinical trial.

SO: Ophthalmology

YR: 2012

VL: 119

NO: 10

PG: 2014-2020

XR: EMBASE 2012585015

KY: adult // anisometropia/th [Therapy] // article // astigmatism/th [Therapy] // controlled study // *custom spectacles // female // follow up // human // major clinical study // male // outcome assessment // patient satisfaction // priority journal // prospective study // quality of life // randomized controlled trial // *ready made spectacles // *refraction error/th [Therapy] // *spectacles // *uncorrected refractive error/th [Therapy] // *vision

DOI: <http://dx.doi.org/10.1016/j.ophtha.2012.03.051>

AB: Purpose: To evaluate patient-reported outcome measures with the use of ready-made spectacles (RMS) and custom spectacles (CS) in an adult population in India with uncorrected refractive error (URE). Design: Prospective, double-masked, randomized trial with 1-month follow-up. Participants: A total of 363 adults aged 18 to 45 years with <1 diopter (D) of URE (RMS, n = 183; CS, n = 180). Intervention: All participants received complete refraction and were randomized to receive CS (full sphero-cylindrical correction) or RMS based on the spherical equivalent for the eye with lower refractive error but limited to the powers in the RMS inventory. Main Outcome Measures: Visual function and quality of life (VFQoL) instrument and participant satisfaction. Results: Rasch scores for VFQoL increased from 1.14 to 4.37 logits in the RMS group and from 1.11 to 4.72 logits in the CS group: respective mean changes of 3.23 (95% confidence interval [CI], 2.90-3.56) vs. 3.61 (95% CI, 3.34-3.88), respectively. Mean patient satisfaction also increased by 1.83 points (95% CI, 1.60-2.06) on a 5-point Likert scale in the RMS group and by 2.04 points (95% CI, 1.83-2.24) in the CS group. In bivariate analyses, CS was not associated with increased VFQoL or patient satisfaction compared with the RMS group. In the full multivariable linear regression, the CS group had greater improvement when compared with those receiving RMS (+0.45 logits; 95% CI, 0.02-0.88), and subjects with astigmatism >2.00 D had significantly less improvement (-0.99 logits; 95% CI, -1.68 to -0.30) after controlling for demographic and vision-related characteristics. In multivariable analysis, increased change in patient satisfaction was related to demographic and optical characteristics, but not spectacle group. Conclusions: Ready-made spectacles produce large but slightly smaller improvements in VFQoL and similar satisfaction with vision at 1-month follow-up when compared with CS. Ready-made spectacles are suitable for the majority of individuals with URE in our study population, although those with high degrees of astigmatism may benefit from a trial of CS. This study provides further evidence for the use of RMS in settings where CS are unavailable or unaffordable, or refractive services are inaccessible to those in need. Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article. 2012 American Academy of Ophthalmology.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/143/CN-00902143/frame.html>

Record #105 of 370



ID: CN-00908058

AU: Srivastava S

AU: Gupta D

AU: Naz A

AU: Rizvi MM

AU: Singh PK

TI: Effects of preoperative single dose Etoricoxib on postoperative pain and sleep after lumbar diskectomy: prospective randomized double blind controlled study.

SO: Middle East journal of anesthesiology

YR: 2012

VL: 21

NO: 5

PG: 725-30

PM: PUBMED 23265037

XR: EMBASE 23265037


PT: Journal: Article

KY: Adolescent;Cyclooxygenase 2 Inhibitors [therapeutic use];Diskectomy;Double-Blind Method;Lumbar Vertebrae [surgery];Pain, Postoperative [drug therapy];Patient Satisfaction;Prospective Studies;Pyridines [therapeutic use];Sleep [drug effects];Sulfones [therapeutic use];Adult[checkword];Humans[checkword];Middle Aged[checkword]

AB: BACKGROUND: Etoricoxib, a selective Cox-2 inhibitor has been found to be effective in the management of acute pain. This study evaluates the effect of preoperative use of oral Etoricoxib on post operative pain relief and sleep in patients undergoing single level diskectomy. METHODS: In this prospective, randomized, controlled study, forty four patient (ASA 1 & 2, age 18-60 years) scheduled to undergo single level lumber diskectomy were given either placebo (control group) or Etoricoxib 120 mg orally one hour before surgery. Post operatively fentanyl intravenous (IV) PCA pump was started. Visual analog score (VAS) was assessed at 0, 6, 12, 18 and 24 hours at rest and movement. Primary end point was total pain relief over 24 hours. Sleep overnight, total fentanyl consumption, incidence of nausea and vomiting, intra-operative blood loss and patient satisfaction were noted. RESULTS: Forty three patients completed the study. Reductions in VAS at rest and on movement were observed in

the Etoricoxib group when compared with the Control group at all the intervals till 24 hours postoperatively, except on movement at 24 hours postoperative ($P < 0.05$). Total fentanyl consumption (microg/kg/hr) was higher in Control group ($P = 0.007$). More patients in Etoricoxib group had a contented facial expression ($p = 0.003$), relaxed body language ($p = 0.00$) and better sleep at night than control group ($p = 0.0004$). CONCLUSION: Single preoperative oral dose (120 mg) of Etoricoxib, given one hour before surgery, has significantly reduced the post operative pain at rest and movement and improved sleep in patients undergoing single level discectomy without any side effects and with good patient satisfaction.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/058/CN-00908058/frame.html>

Record #106 of 370 

ID: CN-00918837

AU: Gupta D

AU: Rusin K

TI: Videolaryngoscopic endotracheal intubation (glidescopespi) of morbidly obese patients in semi-erect position: A comparison with rapid sequence induction in supine position.

SO: Middle East journal of anesthesiology

YR: 2012

VL: 21

NO: 6

PG: 843-50

PM: PUBMED 23634566

XR: EMBASE 23634566


PT: Journal: Article

KY: adolescent // adult // aged // article // *bariatric surgery // comparative study // controlled clinical trial // controlled study // *endotracheal intubation // human // *laryngoscopy // methodology // middle aged // *morbid obesity/su [Surgery] // *patient positioning // prospective study // randomized controlled trial // supine position // videorecording

AB: Background: In regards to peri-anesthetic morbidity considerations, morbidly obese patients often have full stomach for extended periods secondary to delayed gastric emptying.

Additionally, they may have difficulty lying supine because of multiple reasons. Study Objectives: The purpose of the study was to compare endotracheal intubation of morbidly obese patients placed in semi-erect position with the rapid sequence induction in the supine position using GlideScope video laryngoscopy. Methods: A prospective randomized study was conducted in ASA I-III patients aged 18-65 years who were scheduled for bariatric surgery. Group A (Study Group): General anesthesia was induced in the semi-erect position, and endotracheal intubation was performed by the investigator positioned in front of the patient. The GlideScope blade was held in the right hand of the investigator during intubation and endotracheal tube with rigid stylet was inserted using the left hand. Group B (Control Group): General anesthesia was induced and patient's trachea intubated in the standard supine position. Results: 39 patients underwent endotracheal intubation in semi-erect position (Study Group) and 37 patients underwent endotracheal intubation in supine position (Control Group). No differences were observed in the intubation parameters or patient safety. Intubation times required to secure patients' airways were not significantly insignificant ($p = 0.42$) between the two groups; desaturation episodes occurred 50% less frequently (though insignificant $p = 0.42$) in the semierect group. Conclusion: This is the first prospective study demonstrating endotracheal intubation with GlideScope in the semi-erect position as comparable to standard supine position intubation. Moreover, gravity-directed and aligned biomechanics in the semi-erect position may be ergonomically more efficient for intubating morbidly obese patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/837/CN-00918837/frame.html>

Record #107 of 370 

ID: CN-00900771

AU: Rokem A

AU: Landau AN

AU: Prinzmetal W

AU: Wallace DL

AU: Silver MA

AU: D'Esposito M

TI: Modulation of inhibition of return by the dopamine D2 receptor agonist bromocriptine depends on individual DAT1 genotype.

SO: Cerebral cortex (New York, N.Y. : 1991)

YR: 2012

VL: 22

NO: 5

PG: 1133-8

XR: EMBASE 2012231806

PT: Journal: Article

KY: adult // allele // article // *attention // controlled clinical trial // controlled study // corpus striatum // crossover procedure // dopaminergic transmission // double blind procedure // drug blood level // female // genotype // human // human experiment // male // normal human // Parkinson disease // priority journal // task performance // *bromocriptine/ct [Clinical Trial] // *bromocriptine/cr [Drug Concentration] // *bromocriptine/po [Oral Drug Administration] // *bromocriptine/pd [Pharmacology] // dopamine/ec [Endogenous Compound] // dopamine transporter/ec [Endogenous Compound] // placebo

DOI: 10.1093/cercor/bhr185

AB: Involuntary visual spatial attention is captured when a salient cue appears in the visual field. If a target appears soon after the cue, response times to targets at the cue location are faster relative to other locations. However, after longer cue-target intervals, responses to targets at the cue location are slower, due to inhibition of return (IOR). IOR depends on striatal dopamine (DA) levels: It varies with different alleles of the DA transporter gene DAT1 and is reduced in patients with Parkinson's disease, a disease characterized by reduced striatal dopaminergic transmission. We examined the role of DA in involuntary attention and IOR by administering the DA D2 receptor-specific agonist bromocriptine to healthy human subjects. There was no effect of either DAT1 genotype or bromocriptine on involuntary attention, but participants with DAT1 alleles predicting higher striatal DA had a larger IOR. Furthermore, bromocriptine increased the magnitude of IOR in participants with low striatal DA but abolished the IOR in subjects with high striatal DA. This inverted U-shaped pattern resembles previously described relationships between DA levels and performance on cognitive tasks and suggests an involvement of striatal DA in IOR that does not include a role in involuntary attention. 2011 The Author.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/771/CN-00900771/frame.html>

Record #108 of 370



ID: CN-00897149

AU: Berghmans J

AU: Weber F

AU: Akoleyen C

AU: Utens E

AU: Adriaenssens P

AU: Klein J

AU: Himpe D

TI: Audiovisual aid viewing immediately before pediatric induction moderates the accompanying parents' anxiety.

SO: Paediatric Anaesthesia

YR: 2012

VL: 22

NO: 4

PG: 386-392

XR: EMBASE 2012142590


KY: ambulatory surgery // Amsterdam preoperative anxiety and information scale // *anesthesia induction // anesthetist // *anxiety // article // *audiovisual equipment // child // controlled study // female // human // major clinical study // male // operating room // *parent // pediatric anesthesia // preschool child // priority journal // randomized controlled trial // rating scale // school child // single blind procedure // visual analog scale

DOI: <http://dx.doi.org/10.1111/j.1460-9592.2011.03767.x>

AB: Background: Parents accompanying their child during induction of anesthesia experience stress. The impact of audiovisual aid (AVA) on parental state anxiety and assessment of the child's anxiety at induction have been studied previously but need closer scrutiny. Methods: One hundred and twenty parents whose children were scheduled for day-care surgery entered this randomized, controlled study. The intervention group (n = 60) was exposed to an AVA in the holding area. Parental anxiety was measured with the Spielberger State-Trait Anxiety Inventory and the Amsterdam Preoperative Anxiety and Information Scale (APAIS) at three time points: (i) on admission [T1]; (ii) in the holding area just before entering the operating theater [T2]; and (iii) after leaving [T3]. Additionally, at [T3], both parent and attending anesthetist evaluated the child's anxiety using a visual analogue scale. The anesthetist also filled out the Induction Compliance Checklist. Results: On the state anxiety subscale, APAIS parental anxiety at T2 (P = 0.015) and T3 (P = 0.009) was lower in the AVA intervention group than in the control group. After induction, the child's anxiety rating by the anesthetist was significantly lower than by the parent, in both intervention and control groups. Conclusions: Preoperative AVA shown to parents immediately before induction moderates the increase in anxiety associated with the anesthetic induction of their child. Present results suggest that behavioral characteristics seem better predictors of child's anxiety during induction than

anxiety ratings per se and that anesthetists are better than parents in predicting child's anxiety during induction. 2011 Blackwell Publishing Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/149/CN-00897149/frame.html>

Record #109 of 370 

ID: CN-00901884

AU: Das B

AU: Jamil SN

AU: Mitra S

AU: Varshney RK

TI: Comparison of three supraglottic devices in anesthetised paralyzed children undergoing elective surgery.

SO: Saudi journal of anaesthesia

YR: 2012

VL: 6

NO: 3

PG: 224-8

XR: EMBASE 2012596319

PT: Journal: Article


KY: abdominal surgery // airway pressure // anesthesia induction // article // child // *classic laryngeal mask airway // controlled study // *devices // *elective surgery // female // general anesthesia // hemodynamics // human // *i gel airway // inguinal region // intermethod comparison // major clinical study // male // oxygen saturation // preschool child // priority journal // *proseal laryngeal mask airway // prospective study // randomized controlled trial // single blind procedure // *supraglottic device // teaching hospital // tertiary health care // midazolam // sevoflurane

DOI: 10.4103/1658-354X.101212

AB: Context: The newest variation of the i-gel supraglottic airway is a pediatric version. Aims: This study was designed to investigate the usefulness of the size 2 i-gel compared with the ProSeal laryngeal mask airway (PLMA) and classic laryngeal mask airway (cLMA) of the same

size in anesthetized, paralyzed children. Settings and design: A prospective, randomized, single-blinded study was conducted in a tertiary care teaching hospital. Methods: Ninety ASA grade I-II patients undergoing lower abdominal, inguinal and orthopedic surgery were included in this prospective study. The patients were randomly assigned to the i-gel, PLMA and cLMA groups (30 patients in each group). Size 2 supraglottic airway was inserted according to the assigned group. We assessed ease of insertion, hemodynamic data, oropharyngeal sealing pressure and postoperative complications. Results: There were no differences in the demographic and hemodynamic data among the three groups. The airway leak pressure of the i-gel group (27.12.6 cmH₂O) was significantly higher than that of the PLMA group (22.731.2 cmH₂O) and the cLMA group (23.632.3 cmH₂O). The success rates for first attempt of insertion were similar among the three devices. There were no differences in the incidence of postoperative airway trauma, sore throat or hoarse cry in the three groups. Conclusions: Hemodynamic parameters, ease of insertion and postoperative complications were comparable among the i-gel, PLMA and cLMA groups, but airway sealing pressure was significantly higher in the i-gel group.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/884/CN-00901884/frame.html>

Record #110 of 370 

ID: CN-00897157

AU: Bhandari S

AU: Haleem S

AU: Kamran Habib S

AU: Sharma D

AU: Varshney R

AU: Ali QE

TI: A randomized trial of epidural volume extension by sequential combined spinal epidural anesthesia using three different techniques.

SO: The Kuwait medical journal

YR: 2012

VL: 44

NO: 1

PG: 30-4

XR: EMBASE 2012141036

PT: Journal: Article

KY: anesthesia mechanism // article // controlled study // double blind procedure // *epidural anesthesia // female // human // local anesthesia // major clinical study // male // motor nerve block // nerve block // prospective study // randomized controlled trial // *spinal anesthesia // *spinal epidural anesthesia // bupivacaine/ct [Clinical Trial] // fentanyl/ct [Clinical Trial]

AB: Objective(s): Sequential combined spinal epidural anesthesia (SCSEA) is gaining popularity in ASA grade III/IV, elderly, low cardiac output state and high risk patients. In view of contradicting results related to sensori-motor characteristics, we undertook this study with the null hypothesis that epidural volume extension (EVE) with local anesthetic or normal saline results in augmentation of initial intrathecal block. Design: Prospective, randomized, double blind study Settings: J N Medical College, Aligarh Muslim University, Aligarh, India Subjects: Seventy-five ASA I/II patients divided into three groups and operated upon from September 2007 to January 2009 Intervention(s): Group I received 1.5 ml bupivacaine (0.5%) + 25 mug fentanyl in subarachnoid space and epidural catheter was inserted without any top ups. In group II & III with the same technique top ups were given after 10 minutes of the intrathecal block in the form of either 10 ml NS or 10 ml of 0.125% bupivacaine. Main Outcome Measure(s): Augmentation of initial intrathecal block Results: Significant increase in height of block was seen after EVE by different techniques of epidural top up ($T4.64 \pm 0.86$ & $T3.92 \pm 0.99$ in group II & III respectively, $p\text{-value} < 0.05$) as compared to group I ($T7.12 \pm 0.83$). The average increase was 3.12 ± 0.97 and 3.48 ± 1.35 segments in group II & III respectively as compared to 0.48 ± 0.51 segments in group I. Conclusion: Height of low-dose intrathecal block can be enhanced by SCSE using EVE effect even with normal saline.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/157/CN-00897157/frame.html>

Record #111 of 370



ID: CN-00896523

AU: Kanazi GE

AU: Ayoub CM

AU: Aouad M

AU: Abdallah F

AU: Sfeir PM

AU: Adham A-BF

AU: El-Khatib MF

TI: Subpleural block is less effective than thoracic epidural analgesia for post-thoracotomy pain: A randomised controlled study.

SO: European Journal of Anaesthesiology

YR: 2012

VL: 29

NO: 4

PG: 186-191

XR: EMBASE 2012214115

KY: adult // APACHE // article // clinical article // continuous infusion // controlled study // coughing // double blind procedure // female // follow up // human // hypotension/si [Side Effect] // intermethod comparison // male // outcome assessment // postoperative nausea/dt [Drug Therapy] // *postoperative pain/co [Complication] // *postoperative pain/dt [Drug Therapy] // postoperative period // postoperative vomiting/dt [Drug Therapy] // randomized controlled trial // *subpleural analgesia // *thoracotomy // *thorax epidural anesthesia // visual analog scale // adrenalin/ae [Adverse Drug Reaction] // adrenalin/dt [Drug Therapy] // bupivacaine/ae [Adverse Drug Reaction] // bupivacaine/dt [Drug Therapy] // fentanyl // glycopyrronium bromide // lidocaine // midazolam // ondansetron/dt [Drug Therapy] // ondansetron/iv [Intravenous Drug Administration] // paracetamol/dt [Drug Therapy] // paracetamol/iv [Intravenous Drug Administration] // propofol // rocuronium

DOI: <http://dx.doi.org/10.1097/EJA.0b013e32834fcef7>

AB: Context Thoracic epidural and paravertebral blocks provide adequate analgesia for postoperative thoracotomy pain. Both procedures are usually performed percutaneously with considerable failure rates. A subpleural catheter placed in the space posterior to the parietal pleura and alongside the paravertebral area may provide superior postoperative pain relief. Objective To compare subpleural analgesia with thoracic epidural analgesia in patients undergoing thoracotomy. Design Randomised, double-blind study. Setting A tertiary care University Medical Centre between 26 June 2008 and 21 March 2011. Patients Forty-two patients scheduled for elective posterolateral thoracotomy. Patients with American Society of Anesthesiologists physical status 4, with a previous history of thoracotomy, on chronic pain medications or with a contraindication to receiving local anaesthetics or thoracic epidural block were excluded from the study. Interventions Patients were randomised to receive either subpleural analgesia or thoracic epidural analgesia for 24-h post-thoracotomy pain control. Main outcome measures A visual analogue scale was used to assess pain at rest and on coughing during the first 24 h postoperatively and the incidence of hypotension was recorded. Results Patients who received subpleural analgesia had higher visual analogue scores at rest and on coughing than those who received thoracic epidural analgesia. Seven patients who started with subpleural analgesia were treated with thoracic epidural analgesia at a mean (SD)

of 3.9 (4.8) h. The remaining 14 patients had a median (IQR [range]) visual analogue score of 5 cm (4-5 [3-6]) at rest and were maintained on subpleural analgesia until the end of the study. The visual analogue score at rest was <7cm in all 21 patients who received thoracic epidural analgesia and none was switched to subpleural analgesia during the study. None of the patients in the subpleural analgesia group experienced hypotension compared with five of the 21 patients in the thoracic epidural analgesia group (P=0.047). Conclusion Thoracic epidural analgesia is superior to subpleural analgesia in relieving post-thoracotomy pain. 2012 Copyright European Society of Anaesthesiology.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/523/CN-00896523/frame.html>

Record #112 of 370



ID: CN-00903757

AU: Abi Zeid Daou R

AU: Abdelnour Lattouf N

TI: Evaluating the effects of soft tissue manual therapy among women presenting low back pain following epidural anesthesia in obstetrics: A randomized, controlled study. [French]

SO: Kinesithérapie

YR: 2012

VL: 12

NO: 125

PG: 52-9

XR: EMBASE 2012408647

PT: Journal: Review

KY: adult // clinical article // clinical effectiveness // controlled study // epidural anesthesia // female // human // *low back pain/th [Therapy] // *manipulative medicine // neurophysiology // primipara // randomized controlled trial // review // therapy effect // vaginal delivery

DOI: 10.1016/j.kine.2011.11.001

AB: Introduction: Low back pain is common in women who have undergone epidural anesthesia during childbirth. It is instant, limited functionality of the lumbar spine and reduced amplitudes. The treatment is medical, physical agents or manual. Methods: Twenty primiparas with low back pain, who had an average age of 31.5 + 3.35 years, who had given vaginal birth

delivery and had received epidural anesthesia, participated in our experiments over a period of 4 weeks. A group of 10 women has received treatment under the terms of manual treatment (1 s/s) while the second group received physical agents treatment (2 m/s). Results: Both groups had comparable improvement of their variables (except for the Slump test). An advantage in favor of manual treatment was noted with obtaining the same effect in 4 weeks by treatment of four sessions instead of eight. Conclusion: We found a difference due to the use of both treatments. The observed results encourage us to continue to better understand the associated phenomena with neurophysiology. Level of evidence: III. 2012 Elsevier Masson SAS. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/757/CN-00903757/frame.html>

Record #113 of 370



ID: CN-00897196

AU: Nichols JJ

AU: Bickle KM

AU: Zink RC

AU: Schiewe MD

AU: Haque RM

AU: Nichols KK

TI: Safety and efficacy of topical azithromycin ophthalmic solution 1.0% in the treatment of contact lens-related dry eye.

SO: Eye and Contact Lens

YR: 2012

VL: 38

NO: 2

PG: 73-79

XR: EMBASE 2012134042

KY: adult // antibiotic therapy // article // breast disease/si [Side Effect] // chemosis/si [Side Effect] // clinical article // conjunctival hyperemia/si [Side Effect] // *contact lens // *contact lens related dry eye/co [Complication] // *contact lens related dry eye/dt [Drug Therapy] // controlled study // drug efficacy // drug safety // drug withdrawal // *dry eye/co

[Complication] // *dry eye/dt [Drug Therapy] // dysmenorrhea/si [Side Effect] // eye infection/si [Side Effect] // eye irritation/si [Side Effect] // eye pain/si [Side Effect] // female // human // intraocular foreign body/si [Side Effect] // male // mediastinum disease/si [Side Effect] // nose congestion/si [Side Effect] // open study // osmolarity // priority journal // punctate keratitis/si [Side Effect] // questionnaire // randomized controlled trial // respiratory tract disease/si [Side Effect] // rhinopharyngitis/si [Side Effect] // sinus congestion/si [Side Effect] // thorax disease/si [Side Effect] // topical treatment // urogenital tract disease/si [Side Effect] // visual acuity // *azithromycin/ae [Adverse Drug Reaction] // *azithromycin/ct [Clinical Trial] // *azithromycin/dt [Drug Therapy] // *azithromycin/tp [Topical Drug Administration] // tetryzoline

DOI: <http://dx.doi.org/10.1097/ICL.0b013e31823ff229>

AB: PURPOSE: The purpose of this pilot study was to evaluate the safety and efficacy of azithromycin ophthalmic solution 1% in patients with contact lens-related dry eye (CLDE). **METHODS:** This was a 4-week, single-center, open-label clinical trial in patients diagnosed with CLDE using the Contact Lens Dry Eye Questionnaire (CLDEQ). Fifty patients were enrolled in this study. The patients were randomized to 1 of 2 treatment groups: azithromycin ophthalmic solution administered bid on days 1 and 2 and on days 3 to 29+/-1 or Visine for Contacts rewetting drops administered qid on days 1 to 29+/-1. The patient diaries were used daily to collect data on comfortable and total contact lens wear time and ocular dryness throughout the treatment period. Tear osmolarity, fluorescein corneal staining, and visual acuity were also assessed during clinic visits. **RESULTS:** Fifty patients were enrolled, and 44 completed the study. One patient discontinued in the azithromycin group, and five patients discontinued in the rewetting drops group because of adverse events. A statistically significant increase in mean comfortable contact lens wear time from baseline was observed for the subjects treated with azithromycin ophthalmic solution as compared with the subjects treated with rewetting drops at week 4 ($P=0.004$; primary endpoint), in addition to weeks 2 and 3. The improvement in the mean comfortable wear time for the patients in the azithromycin treatment group exceeded 2 hrs throughout the treatment period (weeks 1-4). No significant differences were observed between the groups for total wear time, low contrast visual acuity, or tear osmolarity. Subject-rated ocular dryness (PM time assessments) was significantly improved from baseline in the subjects treated with azithromycin ophthalmic solution as compared with those treated with rewetting drops at weeks 2 and 3 endpoints ($P=0.015$ for each week). Additionally, a statistical difference was observed in favor of the azithromycin treatment group at week 2 for the subjects reclassifying as nondry eye as determined by the CLDEQ ($P=0.05$). **CONCLUSIONS:** Treatment with topical azithromycin ophthalmic solution was well tolerated and resulted in a significant improvement in comfortable contact lens wear time in the patients with CLDE. 2012 Lippincott Williams & Wilkins.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/196/CN-00897196/frame.html>

Record #114 of 370



ID: CN-00901110

AU: Musallam KM

AU: Nasreddine W

AU: Beydoun A

AU: Hourani R

AU: Hankir A

AU: Koussa S

AU: Haidar M

AU: Taher AT

TI: Brain positron emission tomography in splenectomized adults with beta-thalassemia intermedia: Uncovering yet another covert abnormality.

SO: Annals of hematology

YR: 2012

VL: 91

NO: 2

PG: 235-41

XR: EMBASE 2012108860

PT: Journal: Article

KY: adult // article // *beta thalassemia // *brain disease/di [Diagnosis] // brain function // clinical article // computer assisted tomography // controlled clinical trial // controlled study // disease association // dry weight // female // frontal lobe // histopathology // human // human tissue // intermethod comparison // iron overload // liver // male // nuclear magnetic resonance imaging // occipital lobe // parietal lobe // *positron emission tomography // priority journal // risk factor // sensitivity and specificity // sex ratio // *splenectomy // temporal lobe // ferritin/ec [Endogenous Compound] // fluorodeoxyglucose f 18

DOI: 10.1007/s00277-011-1291-3

AB: Covert brain infarction is an emerging concern in patients with beta-thalassemia intermedia (TI). We have recently observed a high prevalence (60%) of silent brain infarction on brain magnetic resonance imaging (MRI) in 30 splenectomized adults with TI. In this work, we further evaluate cerebral involvement in the same 30 patients using fluorodeoxyglucose positron emission tomography-computed tomography (PET-CT) scanning. The median age was

32 years (range, 18-54 years) with a male to female ratio of 13:17. Nineteen patients (63.3%) had evidence of decreased neuronal function on PET-CT. Involvement was mostly left sided, multiple, and most commonly in the temporal and parietal lobes. Elevated liver iron concentration, beyond 15 mg Fe/g dry weight, characterized patients with decreased neuronal function. The concordance rate between brain MRI and PET-CT for the detection of brain abnormality was only 36.7% (Kappa 0.056, P = 0.757), highlighting that both modalities reveal different types of brain pathology. Decreased neuronal function is a common finding in patients with TI and is associated with iron overload. Moreover, the addition of PET-CT to MRI identifies a greater proportion of TI patients with silent neuroimaging abnormalities. 2011 Springer-Verlag.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/110/CN-00901110/frame.html>

Record #115 of 370

ID: CN-00895317

AU: Saleh SS

AU: Freire C

AU: Morris-Dickinson G

AU: Shannon T

TI: An effectiveness and cost-benefit analysis of a hospital-based discharge transition program for elderly medicare recipients.

SO: Journal of the American Geriatrics Society

YR: 2012

VL: 60

NO: 6

PG: 1051-1056


XR: EMBASE 2012337074

KY: aged // article // controlled study // *cost benefit analysis // *elderly care // female // hospital discharge // hospital readmission // human // major clinical study // male // medical record // medicare // patient care // randomized controlled trial

DOI: <http://dx.doi.org/10.1111/j.1532-5415.2012.03992.x>

AB: OBJECTIVE: To investigate the business case of postdischarge care transition (PDCT) among Medicare beneficiaries by conducting a cost-benefit analysis. DESIGN: Randomized controlled trial. SETTING: A general hospital in upstate New York State. PARTICIPANTS: Elderly Medicare beneficiaries being treated from October 2008 through December 2009 were randomly selected to receive services as part of a comprehensive PDCT program (intervention-173 patients) or regular discharge process (control-160 patients) and followed for 12 months. INTERVENTION: The intervention comprised five activities: development of a patient-centered health record, a structured discharge preparation checklist of critical activities, delivery of patient self-activation and management sessions, follow-up appointments, and coordination of data flow. MEASUREMENTS: Cost-benefit ratio of the PDCT program; self-management skills and abilities. RESULTS: The 1-year readmission analysis revealed that control participants were more likely to be readmitted than intervention participants (58.2% vs 48.2%; $P = .08$); with most of that difference observed in the 91 to 365 days after discharge. Findings from the cost-benefit analysis revealed a cost-benefit ratio of 1.09, which indicates that, for every \$1 spent on the program, a saving of \$1.09 was realized. In addition, participating in a care transition program significantly enhanced self-management skills and abilities. CONCLUSION: Postdischarge care transition programs have a dual benefit of enhancing elderly adults' self-management skills and abilities and producing cost savings. This study builds a case for the inclusion of PDCT programs as a reimbursable service in benefit packages. 2012, Copyright the Authors Journal compilation 2012, The American Geriatrics Society.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/317/CN-00895317/frame.html>

Record #116 of 370 

ID: CN-00902442

AU: Sanchez-Ramos J

AU: Cimino C

AU: Avila R

AU: Rowe A

AU: Chen R

AU: Whelan G

AU: Lin X

AU: Cao C

AU: Ashok R

TI: Pilot study of granulocyte-colony stimulating factor for treatment of Alzheimer's disease.

SO: Journal of Alzheimer's Disease

YR: 2012

VL: 31

NO: 4

PG: 843-855

XR: EMBASE 2012545972

KY: adult // aged // *Alzheimer disease/dt [Drug Therapy] // article // backache/co [Complication] // cerebrospinal fluid level // clinical article // cognition // controlled study // crossover procedure // double blind procedure // drug effect // drug safety // drug tolerability // female // headache/co [Complication] // human // leukocyte count // lumbar puncture // male // myalgia/si [Side Effect] // nausea and vomiting/co [Complication] // neuropsychological test // neutrophil count // nuclear magnetic resonance imaging // *paired associate learning // pattern recognition // pilot study // priority journal // randomized controlled trial // recognition // side effect/si [Side Effect] // spatial memory // amantadine // amphetamine plus dexamphetamine // amyloid beta protein[1-40]/ec [Endogenous Compound] // amyloid beta protein[1-42]/ec [Endogenous Compound] // donepezil // gamma interferon/ec [Endogenous Compound] // granulocyte colony stimulating factor receptor/ec [Endogenous Compound] // granulocyte macrophage colony stimulating factor/ec [Endogenous Compound] // interleukin 10/ec [Endogenous Compound] // interleukin 15/ec [Endogenous Compound] // interleukin 17F/ec [Endogenous Compound] // interleukin 1alpha/ec [Endogenous Compound] // interleukin 4/ec [Endogenous Compound] // interleukin 6/ec [Endogenous Compound] // memantine // nonsteroid antiinflammatory agent // *recombinant granulocyte colony stimulating factor/ae [Adverse Drug Reaction] // *recombinant granulocyte colony stimulating factor/ct [Clinical Trial] // *recombinant granulocyte colony stimulating factor/dt [Drug Therapy] // tau protein/ec [Endogenous Compound] // venlafaxine

DOI: <http://dx.doi.org/10.3233/JAD-2012-120196>

AB: Human granulocyte colony-stimulating-factor (G-CSF) is widely used for treatment of neutropenia and to mobilize stem/progenitor cells for bone marrow transplantation. In studies of thousands of healthy donor subjects treated with G-CSF to mobilize stem/progenitor cells, the side-effect profile has been reported to be mild and reversible. In pre-clinical studies, G-CSF was reported to improve spatial learning performance and to markedly reduce amyloid deposition in hippocampus and entorhinal cortex in a murine model of Alzheimer's disease (AD). The present study investigated the effects of a five day schedule of G-CSF administration on tolerability, safety, and cognition in eight patients with mild to moderate stage AD. A double-blind placebo control, cross-over design was implemented. Treatment with G-CSF did not result in serious adverse events. The most common and expected side effects were transient increases in white blood cell count, myalgias and diffuse aching that improved with

non-steroidal anti-inflammatory medications. Of a battery of cognitive tests administered using the CANTAB computerized system, only the mean paired associate learning (PAL total trials adjusted) was significantly improved at the final visit of the study compared to baseline values ($p < 0.05$). There were no significant differences in amyloid-beta₁₋₄₂ levels in cerebrospinal fluid measured two weeks after G-CSF and two weeks after placebo treatments. In conclusion, administration of G-CSF in a dosage regimen commonly used for bone marrow donors was well tolerated and safe, and provided a signal of positive change in a hippocampal-dependent task of cognitive performance. 2012 - IOS Press and the authors. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/442/CN-00902442/frame.html>

Record #117 of 370



ID: CN-00887318

AU: Ferris SH

AU: Schmitt FA

AU: Saxton J

AU: Richardson S

AU: MacKell J

AU: Sun Y

TI: Analyzing the impact of 23 mg/day donepezil on language dysfunction in moderate to severe Alzheimer's disease.

SO: Alzheimer's research & therapy

YR: 2011

VL: 3

NO: 3

XR: EMBASE 2011468765

PT: Journal: Article

KY: *Alzheimer disease // alzheimer disease cooperative study activities of daily living inventory // article // clinical assessment tool // clinician interview based impression of change plus caregiver input // clinician interview based impression of severity plus caregiver input // comparative effectiveness // controlled study // disease severity // double blind procedure //

drug dose comparison // drug dose increase // drug efficacy // drug megadose // female // human // *language disability/dt [Drug Therapy] // major clinical study // male // Mini Mental State Examination // parallel design // priority journal // randomized controlled trial // Severe Impairment Battery Language scale // treatment duration // *donepezil/ct [Clinical Trial] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy]

DOI: 10.1186/alzrt84

AB: Introduction. Progressive language impairment is among the primary components of cognitive decline in Alzheimer's disease (AD). Because expressive and receptive language help to maintain emotional connections to caregivers and support the management of AD patients' functional needs, language plays a critical role in patients' emotional and physical health. Using data from a large prospective clinical trial comparing two doses of donepezil in patients with moderate to severe AD, we performed a post hoc analysis to determine whether a higher dose of donepezil was associated with greater benefits in language function. **Methods.** In the original randomized, double-blind clinical trial, 1,467 patients with moderate to severe AD (baseline Mini-Mental State Examination (MMSE) score 0 to 20) were randomized 2:1 to receive donepezil 23 mg/day or to continue on donepezil 10 mg/day for 24 weeks. In this post hoc analysis, the Severe Impairment Battery-Language scale (SIB-L) and a new 21-item SIB-derived language scale (SIB[lang]) were used to explore differences in language function between the treatment groups. Correlations between SIB-L and SIB[lang] scores and scores on the severe version of the Alzheimer's Disease Cooperative Study-Activities of Daily Living inventory (ADCS-ADL-sev), the Clinician's Interview-Based Impression of Severity-plus caregiver input/Clinician's Interview-Based Impression of Change-plus caregiver input (CIBIS-plus/CIBIC-plus) and the MMSE were also investigated. **Results:** At week 24, treatment with donepezil 23 mg/day was associated with an improvement in language in the full intention-to-treat population, whereas language function declined in the group treated with donepezil 10 mg/day (SIB-L treatment difference 0.8, $P = 0.0013$; SIB[lang] treatment difference 0.8, $P = 0.0009$). Similar results were observed in a cohort of patients with more severe baseline disease (MMSE score 0 to 16). At baseline and week 24, correlations between the SIB-derived language scales and the ADCS-ADL-sev and CIBIC-plus were moderate, but the correlations were stronger between the language scales and the MMSE scores. **Conclusions:** Patients with moderate to severe AD receiving donepezil 23 mg/day showed greater language benefits than those receiving donepezil 10 mg/day as measured by SIB-derived language assessments. Increasing the dose of donepezil to 23 mg/day may provide language benefits in patients with moderate to severe AD, for whom preservation of language abilities is especially critical. ClinicalTrials.gov identifier: NCT00478205. 2011 Ferris et al.; licensee BioMed Central Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/318/CN-00887318/frame.html>



ID: CN-00972887

AU: Maher-Edwards G

AU: Dixon R

AU: Hunter J

AU: Gold M

AU: Hopton G

AU: Jacobs G

AU: Hunter J

AU: Williams P

TI: SB-742457 and donepezil in Alzheimer disease: a randomized, placebo-controlled study.

SO: International journal of geriatric psychiatry

YR: 2011

VL: 26

NO: 5

PG: 536-44

PM: PUBMED 20872778

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Alzheimer Disease [drug therapy];Analysis of Variance;Cholinesterase Inhibitors [therapeutic use];Cognition [drug effects];Indans [therapeutic use];Piperidines [therapeutic use];Quinolines [therapeutic use];Serotonin Antagonists [therapeutic use];Sulfones [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1002/gps.2562

AB: OBJECTIVE: To estimate the treatment effects of SB-742457 and donepezil in Alzheimer disease (AD) in a contemporary clinical trial. METHOD: Randomized, controlled, parallel-group, exploratory study with a 4-week, single-blind, placebo run-in phase and 24-week, double-blind treatment phase. Primary endpoints were Clinician's Interview-Based Impression of Change with caregiver input (CIBIC+) and the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog). RESULTS: One hundred ninety eight subjects with mild-to-moderate probable AD (MMSE scores 12-26) were randomized; 196 were included in the intent-to-treat population (placebo, n=?61; SB-742457 35?mg/day, n=?68; donepezil 10?mg/day, n=?67), and 161 completed. Drug-placebo treatment differences in CIBIC+ score at week 24 were -0.17 (90%

confidence interval [CI]: -0.50, 0.16) for SB-742457 and -0.28 (90% CI: -0.61, 0.05) for donepezil. Drug-placebo treatment differences (90% CI) in change from baseline ADAS-Cog score at Week 24 were -0.4 (-2.2, 1.4) for SB-742457 and -1.2 (-3.0, 0.6) for donepezil. All treatments were generally safe and well tolerated. CONCLUSIONS: In this exploratory study, SB-742457 and donepezil were associated with improvements in global function. Treatment effect on cognition for both SB-742457 and donepezil was smaller than those previously observed in previous clinical studies with donepezil.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/887/CN-00972887/frame.html>

Record #119 of 370 

ID: CN-00887959

AU: Maher-Edwards G

AU: Dixon R

AU: Gold M

AU: Hopton G

AU: Jacobs G

AU: Hunter J

AU: Williams P

TI: SB-742457 and donepezil in Alzheimer disease: A randomized, placebo-controlled study.

SO: International Journal of Geriatric Psychiatry

YR: 2011

VL: 26

NO: 5

PG: 536-544

XR: EMBASE 2011179240

KY: abdominal pain/si [Side Effect] // adult // aged // *Alzheimer disease/dt [Drug Therapy] // article // clinical assessment // cognition // controlled study // creatine kinase blood level // dermatitis/si [Side Effect] // Diagnostic and Statistical Manual of Mental Disorders // disease severity // double blind procedure // drug dose titration // drug safety // drug tolerability // electrocardiogram // female // gamma glutamyl transferase blood level // headache/si [Side

Effect] // human // language // major clinical study // male // memory // Mini Mental State Examination // nausea/si [Side Effect] // neurologic examination // outcome assessment // patient compliance // phase 2 clinical trial // randomized controlled trial // rhinopharyngitis/si [Side Effect] // sample size // semi structured interview // side effect/si [Side Effect] // treatment duration // treatment response // treatment withdrawal // upper abdominal pain/si [Side Effect] // urinary tract infection/si [Side Effect] // xerostomia/si [Side Effect] // *3 phenylsulfonyl 8 (1 piperazinyl)quinoline/ae [Adverse Drug Reaction] // *3 phenylsulfonyl 8 (1 piperazinyl)quinoline/ct [Clinical Trial] // *3 phenylsulfonyl 8 (1 piperazinyl)quinoline/do [Drug Dose] // *3 phenylsulfonyl 8 (1 piperazinyl)quinoline/dt [Drug Therapy] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy] // placebo

DOI: <http://dx.doi.org/10.1002/gps.2562>

AB: Objective: To estimate the treatment effects of SB-742457 and donepezil in Alzheimer disease (AD) in a contemporary clinical trial. Method: Randomized, controlled, parallel-group, exploratory study with a 4-week, single-blind, placebo run-in phase and 24-week, double-blind treatment phase. Primary endpoints were Clinician's Interview-Based Impression of Change with caregiver input (CIBIC+) and the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog). Results: One hundred ninety eight subjects with mild-to-moderate probable AD (MMSE scores 12-26) were randomized; 196 were included in the intent-to-treat population (placebo, n=61; SB-742457 35 mg/day, n=68; donepezil 10 mg/day, n=67), and 161 completed. Drug-placebo treatment differences in CIBIC+ score at week 24 were -0.17 (90% confidence interval [CI]: -0.50, 0.16) for SB-742457 and -0.28 (90% CI: -0.61, 0.05) for donepezil. Drug-placebo treatment differences (90% CI) in change from baseline ADAS-Cog score at week 24 were -0.4 (-2.2, 1.4) for SB-742457 and -1.2 (-3.0, 0.6) for donepezil. All treatments were generally safe and well tolerated. Conclusions: In this exploratory study, SB-742457 and donepezil were associated with improvements in global function. Treatment effect on cognition for both SB-742457 and donepezil was smaller than those previously observed in previous clinical studies with donepezil. Copyright 2010 John Wiley & Sons, Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/959/CN-00887959/frame.html>

Record #120 of 370



ID: CN-00781734

AU: Waldemar G

AU: Gauthier S

AU: Jones R

AU: Wilkinson D

AU: Cummings J

AU: Lopez O

AU: Zhang R

AU: Xu Y

AU: Sun Y

AU: Knox S

AU: Richardson S

AU: Mackell J

TI: Effect of donepezil on emergence of apathy in mild to moderate Alzheimer's disease.

SO: International journal of geriatric psychiatry

YR: 2011

VL: 26

NO: 2

PG: 150-7

PM: PUBMED 20597141

PT: Journal Article; Randomized Controlled Trial

KY: Alzheimer Disease [drug therapy] [psychology];Apathy [drug effects];Brief Psychiatric Rating Scale;Cholinesterase Inhibitors [therapeutic use];Indans [therapeutic use];Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Severity of Illness Index;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1002/gps.2507

AB: OBJECTIVE: To determine whether donepezil treatment (10 mg/day over 24 weeks) is associated with delayed emergence of apathy in patients with mild to moderate Alzheimer's disease (AD) and to explore relationships between donepezil's effects on apathy and other Neuropsychiatric Inventory (NPI)-measured behavioural symptoms. METHODS: Two randomised, double-blind, parallel-group, placebo-controlled studies that met prespecified criteria and were sufficiently similar to allow data pooling were derived from all donepezil AD clinical trials. Patients scoring from 10 to 26 on baseline Mini-Mental Status Examination were included. A clinical milestone for apathy and other NPI items was defined as the first emergence of a composite score (frequency \times severity) ≥ 3 . Differences in time to event (i.e. milestone) between donepezil- and placebo-treated groups were assessed using the Kaplan-

Meier method and log-rank test. Shift tables were constructed to evaluate clinical milestone status for apathy and other NPI items at baseline and endpoint, and were analysed using the Cochran-Mantel-Haenszel (CMH) test, stratified by baseline status. RESULTS: Of all NPI items, apathy had the highest proportion of subjects scoring ≥ 3 at baseline. Donepezil was superior to placebo on both apathy milestone analyses (time-to-event log-rank test and shift table CMH test, $p = 0.01$). Aberrant motor behaviour demonstrated similar benefit. CONCLUSIONS: Donepezil treatment appears to have resulted in a significant reduction over 6 months of the emergence of apathy in patients with AD. These data suggest that a prospective clinical trial in patients with early AD that includes apathy as a primary outcome measure may be warranted.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/734/CN-00781734/frame.html>

Record #121 of 370



ID: CN-00771338

AU: Reynolds CF

AU: Butters MA

AU: Lopez O

AU: Pollock BG

AU: Dew MA

AU: Mulsant BH

AU: Lenze EJ

AU: Holm M

AU: Rogers JC

AU: Mazumdar S

AU: Houck PR

AU: Begley A

AU: Anderson S

AU: Karp JF

AU: Miller MD

AU: Whyte EM

AU: Stack J

AU: Gildengers A

AU: Szanto K

AU: Bensasi S

AU: Kaufer DI

AU: Kamboh MI

AU: DeKosky ST

TI: Maintenance treatment of depression in old age: a randomized, double-blind, placebo-controlled evaluation of the efficacy and safety of donepezil combined with antidepressant pharmacotherapy.

SO: Archives of general psychiatry

YR: 2011

VL: 68

NO: 1

PG: 51-60

PM: PUBMED 21199965

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living [psychology]; Aging [drug effects] [psychology]; Antidepressive Agents [adverse effects] [therapeutic use]; Cholinesterase Inhibitors [adverse effects] [therapeutic use]; Cognition [drug effects]; Depressive Disorder, Major [diagnosis] [drug therapy] [prevention & control] [psychology]; Double-Blind Method; Drug Therapy, Combination [methods]; Follow-Up Studies; Indans [adverse effects] [therapeutic use]; Nootropic Agents [therapeutic use]; Piperidines [adverse effects] [therapeutic use]; Recurrence [prevention & control]; Treatment Outcome; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

CC: SR-DEPRESSN


DOI: 10.1001/archgenpsychiatry.2010.184

AB: CONTEXT: Cognitive impairment in late-life depression is a core feature of the illness.

OBJECTIVE: To test whether donepezil hydrochloride and antidepressant therapy is superior to placebo and antidepressant therapy in improving cognitive performance and instrumental activities of daily living and in reducing recurrences of depression over 2 years of maintenance treatment. DESIGN: Randomized, double-blind, placebo-controlled maintenance trial. SETTING:

University clinic. PARTICIPANTS: One hundred thirty older adults aged 65 years and older with recently remitted major depression. INTERVENTIONS: Random assignment to maintenance antidepressant pharmacotherapy and donepezil or to maintenance antidepressant pharmacotherapy and placebo. MAIN OUTCOME MEASURES: Global neuropsychological performance, cognitive instrumental activities of daily living, and recurrent depression. RESULTS: Donepezil and antidepressant therapy temporarily improved global cognition (treatment \times time interaction, $F_{2,114} = 3.78$; $P = .03$), but effect sizes were small (Cohen $d = 0.27$, group difference at 1 year). A marginal benefit to cognitive instrumental activities of daily living was also observed (treatment \times time interaction, $F_{2,114} = 2.94$; $P = .06$). The donepezil group was more likely than the placebo group to experience recurrent major depression (35% [95% confidence interval {CI}, 24%-46%] vs 19% [95% CI, 9%-29%], respectively; log-rank $\chi^2 = 3.97$; $P = .05$; hazard ratio = 2.09 [95% CI, 1.00-4.41]). Post hoc subgroup analyses showed that of 57 participants with mild cognitive impairment, 3 of 30 participants (10% [95% CI, 0%-21%]) receiving donepezil and 9 of 27 participants (33% [95% CI, 16%-51%]) receiving placebo had a conversion to dementia over 2 years (Fisher exact test, $P = .05$). The mild cognitive impairment subgroup had recurrence rates of major depression of 44% with donepezil vs 12% with placebo (likelihood ratio = 4.91; $P = .03$). The subgroup with normal cognition ($n = 73$) showed no benefit with donepezil and no increase in recurrence of major depression. CONCLUSIONS: Whether a cholinesterase inhibitor should be used as augmentation in the maintenance treatment of late-life depression depends on a careful weighing of risks and benefits in those with mild cognitive impairment. In cognitively intact patients, donepezil appears to have no clear benefit for preventing progression to mild cognitive impairment or dementia or for preventing recurrence of depression. TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00177671.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/338/CN-00771338/frame.html>

Record #122 of 370 

ID: CN-00810966

AU: Kim KA

AU: Lim JL

AU: Kim C

AU: Park JY

TI: Pharmacokinetic comparison of orally disintegrating and conventional donepezil formulations in healthy Korean male subjects: a single-dose, randomized, open-label, 2-sequence, 2-period crossover study.

SO: Clinical therapeutics

YR: 2011

VL: 33

NO: 7

PG: 965-72

PM: PUBMED 21723605

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Administration, Oral;Area Under Curve;Asian Continental Ancestry Group;Cholinesterase Inhibitors [administration & dosage] [adverse effects] [pharmacokinetics];Cross-Over Studies;Indans [administration & dosage] [adverse effects] [pharmacokinetics];Piperidines [administration & dosage] [adverse effects] [pharmacokinetics];Republic of Korea;Therapeutic Equivalency;Adult[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

DOI: 10.1016/j.clinthera.2011.06.003

AB: BACKGROUND: Donepezil is a potent inhibitor of acetylcholinesterase, an enzyme that is targeted in the treatment of Alzheimer's disease. OBJECTIVE: The purpose of this study was to compare the pharmacokinetic characteristics of orally disintegrating (test) and conventional (reference) donepezil formulations to satisfy the regulatory requirement for marketing. METHODS: A single-center randomized, single-dose, open-label, 2-way crossover study with a 21-day washout period was conducted in 22 healthy volunteers. Plasma samples for the analysis of donepezil were collected up to 240 hours after drug administration. Participants received either reference or test drug formulation of 10 mg donepezil in the first period and the alternative formulation in the second period. Plasma concentrations of donepezil were determined by validated high-performance liquid chromatography coupled to tandem mass spectrometry detection. Pharmacokinetic parameters, including C(max) and AUC, were determined by noncompartmental analysis. ANOVA was carried out using log-transformed C(max) and AUC, and the mean ratios and their 90% CIs were calculated. The safety profiles and tolerabilities of the 2 formulations were also assessed based on laboratory tests, 12-lead ECGs, vital signs, and physical examinations. RESULTS: Of the 22 participants initially enrolled, 18 healthy Korean participants completed both treatment periods. Four subjects did not complete both treatments: 3 subjects withdrew consent for personal reasons, and 1 subject experienced adverse events. No significant differences in pharmacokinetic parameters between the 2 formulations were observed. The mean (SD) age, height, and weight of the participants were 25.8 (4.1) years, 173.6 (5.7) cm, and 68.9 (7.8) kg, respectively. The mean (SD) C(max), AUC(last), and AUC(inf) for the reference formulation were 33.26 (6.58) ng/mL, 1521.69 (344.04) ng × h/mL, and 1691.46 (443.05) ng × h/mL, respectively. Corresponding values for the test formulation were 34.23 (6.79) ng/mL, 1554.33 (390.23) ng × h/mL, and 1718.27 (447.03) ng × h/mL, respectively. The median T(max) was 2 hours (range, 1-3 hours) for the reference and test formulations. The geometric mean ratios (90% CI) between the 2 formulations of donepezil were 102.9 (96.8-109.5) for C(max), 102.3 (96.1-108.9) for AUC(last),

and 101.6 (95.4-108.2) for AUC(0-?), respectively. During the study, 15 and 14 adverse events were reported for the reference and test formulations, respectively, and all were transient, mild, and resolved during the treatment period. These adverse events included 7 cases of nausea, 3 cases of headache, and 1 case each of dizziness, vomiting, chills, and sweating. All adverse events were considered related to the study drugs. CONCLUSION: This study found that the test and reference formulations met the regulatory criteria for pharmacokinetic equivalence in these fasting healthy Korean male subjects. Both donepezil formulations appeared to be generally well tolerated.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/966/CN-00810966/frame.html>

Record #123 of 370 

ID: CN-00788779

AU: Krupp LB

AU: Christodoulou C

AU: Melville P

AU: Scherl WF

AU: Pai LY

AU: Muenz LR

AU: He D

AU: Benedict RH

AU: Goodman A

AU: Rizvi S

AU: Schwid SR

AU: Weinstock-Guttman B

AU: Westervelt HJ

AU: Wishart H

TI: Multicenter randomized clinical trial of donepezil for memory impairment in multiple sclerosis.

SO: Neurology

YR: 2011

VL: 76

NO: 17

PG: 1500-7

PM: PUBMED 21519001

PT: Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Adolescent;Cholinesterase Inhibitors [therapeutic use];Double-Blind Method;Indans [therapeutic use];Memory Disorders [drug therapy] [etiology];Multiple Sclerosis [complications];Neuropsychological Tests;Piperidines [therapeutic use];Treatment Outcome;Verbal Learning [drug effects] [physiology];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

DOI: 10.1212/WNL.0b013e318218107a

AB: OBJECTIVES: The goal of this study was to determine if memory would be improved by donepezil as compared to placebo in a multicenter, double-blind, randomized clinical trial (RCT). METHODS: Donepezil 10 mg daily was compared to placebo to treat memory impairment. Eligibility criteria included the following: age 18-59 years, clinically definite multiple sclerosis (MS), and performance $\geq \frac{1}{2}$ SD below published norms on the Rey Auditory Verbal Learning Test (RAVLT). Neuropsychological assessments were performed at baseline and 24 weeks. Primary outcomes were change on the Selective Reminding Test (SRT) of verbal memory and the participant's impression of memory change. Secondary outcomes included changes on other neuropsychological tests and the evaluating clinician's impression of memory change. RESULTS: A total of 120 participants were enrolled and randomized to either donepezil or placebo. No significant treatment effects were found between groups on either primary outcome of memory or any secondary cognitive outcomes. A trend was noted for the clinician's impression of memory change in favor of donepezil (37.7%) vs placebo (23.7%) ($p = 0.097$). No serious or unanticipated adverse events attributed to study medication developed. CONCLUSIONS: Donepezil did not improve memory as compared to placebo on either of the primary outcomes in this study. CLASSIFICATION OF EVIDENCE: This study provides Class I evidence which does not support the hypothesis that 10 mg of donepezil daily for 24 weeks is superior to placebo in improving cognition as measured by the SRT in people with MS whose baseline RAVLT score was 0.5 SD or more below average.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/779/CN-00788779/frame.html>



ID: CN-00895010

AU: Barrett KM

AU: Brott TG

AU: Brown Jr RD

AU: Carter RE

AU: Geske JR

AU: Graff-Radford NR

AU: McNeil RB

AU: Meschia JF

TI: Enhancing recovery after acute ischemic stroke with donepezil as an adjuvant therapy to standard medical care: Results of a phase iia clinical trial.

SO: Journal of stroke and cerebrovascular diseases

YR: 2011

VL: 20

NO: 3

PG: 177-82

XR: EMBASE 2011238753

PT: Journal: Article


KY: adjuvant therapy // aged // anorexia/si [Side Effect] // article // *brain ischemia // clinical article // cognition // convalescence // depression/si [Side Effect] // drug dose escalation // drug dose reduction // drug efficacy // drug safety // drug tolerability // drug withdrawal // fatigue/si [Side Effect] // female // functional status // human // insomnia/si [Side Effect] // leg cramp/si [Side Effect] // male // medical care // Mini Mental State Examination // multicenter study // muscle cramp/si [Side Effect] // nausea/si [Side Effect] // neurologic disease // priority journal // psychologic test // psychological aspect // randomized controlled trial // treatment outcome // United States // alteplase/iv [Intravenous Drug Administration] // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/po [Oral Drug Administration]

DOI: 10.1016/j.jstrokecerebrovasdis.2010.12.009

AB: Background: Our aim was to assess the safety, tolerability, and efficacy signal of early donepezil administration with regard to enhancing recovery in a diverse acute ischemic stroke population. Methods: This was a multicenter, single-arm, National Institute of Neurological Disorders and Stroke Recombinant Tissue Plasminogen Activator trial-controlled, modified 2-

stage adaptive clinical trial set in 2 tertiary care hospitals in the United States. Adults with ischemic stroke treated within 24 hours after onset of symptoms were included. The intervention studied was donepezil 5 mg/day for 30 days, followed by an increase to 10 mg/day for 60 days. Our main outcome measures included treatment-related adverse events and side effects. The primary favorable outcome was a 90-day National Institutes of Health Stroke Scale (NIHSS) score <1. Neurologic, cognitive, functional, and psychological outcomes were assessed longitudinally. Results: Thirty-three adults (median age 66 years; 59% female; 39% received tissue plasminogen activator) initiated treatment with donepezil. There were no treatment-related serious adverse events. Three participants (9%) discontinued donepezil because of side effects and 3 participants (9%) required a reduction to 5 mg/day after titration to 10 mg/day. Fifteen participants (45%) had a favorable outcome (NIHSS score <1 at day 90), and the study met prespecified criteria for continuing to a randomized trial ($P < .10$). Statistically significant improvements from baseline were observed with several secondary cognitive measures, including the Trail Making Tests and Mini-Mental State Exam ($P < .01$ for both). Conclusions: Adjuvant donepezil therapy initiated within 24 hours of acute ischemic stroke was safe and tolerated at 5 mg/day to 10 mg/day. The study met a priori criteria to move forward with a randomized clinical trial. 2011 by National Stroke Association.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/010/CN-00895010/frame.html>

Record #125 of 370 

ID: CN-00970557

AU: Dong GS

AU: Li X

AU: Jiang QH

AU: Yang HQ

TI: [Effects of donepezil treatment on platelets ? and ? secretase activities in Alzheimer's disease patients].

SO: Zhonghua yi xue za zhi

YR: 2011

VL: 91

NO: 47

PG: 3341-5


PM: PUBMED 22333201

PT: English Abstract; Journal Article; Randomized Controlled Trial; Research Support, U.S. Gov't, Non-P.H.S.

KY: Alzheimer Disease [drug therapy] [metabolism]; Amyloid Precursor Protein Secretases [metabolism]; Blood Platelets [enzymology]; Cholinesterase Inhibitors [therapeutic use]; Indans [therapeutic use]; Piperidines [therapeutic use]; Treatment Outcome; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

AB: OBJECTIVE: To explore the effects of donepezil on the activities of platelet ? and ? secretases in Alzheimer's disease (AD) patients. METHODS: During the period of 2007 - 2010, a total of 76 AD patients received either regular treatment alone or in combination with donepezil (5 mg/d) for a 12-week period. And their effects on ADAS-Cog (Alzheimer's disease assessment scale-cognitive subscale) total and ADL (activity of daily living) scores were measured. The effects of donepezil on ? and ? secretase activities and sAPP? (soluble amyloid precursor protein ?) secretion in AD patients and non-demented patients were detected by fluorescence and Western blot respectively. RESULTS: After the donepezil treatment, the ADAS-Cog scores of the treatment group decreased versus the control [(5.3 ± 4.4) vs (1.7 ± 1.6)]. And the differences were statistically significant (P < 0.01). And the ADL scores of the treatment group decreased versus the control [(41 ± 7) vs. (48 ± 6)]. And the differences were statistically significant (P < 0.05). As compared with that of pre-treatment (50 ± 6), the differences were statistically significant (P < 0.05). The activity of ? secretase increased markedly while that of ? secretase decreased markedly versus the controls [(91% ± 9%) vs (64% ± 8%), P < 0.01; (119% ± 11%) vs (178% ± 17%), P < 0.01]. Both had significant statistical differences with those of pre-treatment (both P < 0.01). As compared with the non-demented group (100% ± 12%, P < 0.001), the sAPP? contents of treatment and control groups were (64% ± 14%, P < 0.01) and (26% ± 8%, P < 0.001) respectively. CONCLUSION: The administration of donepezil in AD patients improves cognitive functions and daily activities as indicated by the decreased ADAS-Cog total scores and ADL scores through the increased activity of ? secretase and the decreased activity of ? secretase. The clinical efficacy of donepezil may be attributed to its pharmacological effects on the regulation of platelet secretase activities.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/557/CN-00970557/frame.html>

Record #126 of 370 

ID: CN-00894787

AU: Amenta F

AU: Carotenuto A

AU: Fasanaro G

AU: Lanari A

AU: Rea R

AU: Traini E

TI: Preliminary results of ASCOMALVA trial on the association of donepezil and choline alfoscerate in Alzheimer's disease with associated cerebrovascular injury. [Italian]

SO: Giornale di gerontologia

YR: 2011

VL: 59

NO: 2

PG: 89-98

XR: EMBASE 2011290156


PT: Journal: Article

KY: adult // aged // *Alzheimer disease/dt [Drug Therapy] // article // basal ganglion // brain ischemia // caregiver burden // *cerebrovascular accident/dt [Drug Therapy] // computer assisted tomography // disease association // disease severity // drug effect // follow up // human // major clinical study // neuroimaging // nuclear magnetic resonance imaging // randomized controlled trial // treatment outcome // white matter // *choline alfoscerate/ct [Clinical Trial] // *choline alfoscerate/cb [Drug Combination] // *choline alfoscerate/dt [Drug Therapy] // *donepezil/ct [Clinical Trial] // *donepezil/cb [Drug Combination] // *donepezil/dt [Drug Therapy] // placebo

AB: This article summarizes the preliminary results of the ongoing (ASCOMALVA) trial on the "association between a cholinesterase inhibitor (ChE-I) and a cholinergic precursor, choline alfoscerate on cognitive deficits in Alzheimer's disease associated with cerebrovascular injury". The trial was designed to assess the effect of the ChE-I donepezil at the daily dose of 10 mg and of choline alfoscerate at the daily dose of 1,200 mg/day on the Mini Mental State Evaluation (MMSE), Basic Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL) and Neuropsychiatric Inventory (NPI). The latter included an evaluation of severity and of caregiver stress (NPIF and NPIS). Currently, the trial has completed the first 6 months of follow-up on 70 of the 210 patients planned. Patients recruited were between 56 and 86 years of age (mean 75 + 10 years) and were required to have a MMSE score between 15 and 24. Patients also needed to have ischemic brain lesions documented by neuroimaging (MRI and/or CT scan), with a score > 2 in at least one subfield (white matter or basal ganglia) according to the New Rating Scale for Age-Related White Matter Changes (ARWMC). Patients were then randomly allocated to the active treatment group (donepezil + choline alfoscerate) or to a reference treatment group (donepezil + placebo). The first 70 patients included in this analysis have been followed for 6 months with evaluations at baseline and at 3 and 6 months. Treatment will be sustained for 24 months and evaluations will be conducted at 3, 6, 9, 12, 18 and 24 months. Patients in the reference treatment group displayed a slight, time- dependent worsening of MMSE, IADL and NPIS scores while there were no noticeable changes in ADL and

NPIF scores. In contrast, treatment with donepezil plus choline alphoscerate did improve all of the different scores except for the ADL. These preliminary results suggest that the addition of a cholinergic precursor like choline alphoscerate to the standard treatment with a ChE-I may represent a way to prolong/increase the beneficial effects of cholinergic therapies in Alzheimer's disease patients with concomitant ischemic cerebrovascular disease. Società Italiana di Gerontologia e Geriatria.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/787/CN-00894787/frame.html>

Record #127 of 370 

ID: CN-00787697

AU: Handen BL

AU: Johnson CR

AU: McAuliffe-Bellin S

AU: Murray PJ

AU: Hardan AY

TI: Safety and efficacy of donepezil in children and adolescents with autism: neuropsychological measures.

SO: Journal of child and adolescent psychopharmacology

YR: 2011

VL: 21

NO: 1

PG: 43-50

PM: PUBMED 21309696

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Adolescent;Autistic Disorder [drug therapy] [physiopathology];Cholinesterase Inhibitors [administration & dosage] [adverse effects] [therapeutic use];Dose-Response Relationship, Drug;Double-Blind Method;Executive Function [drug effects];Indans [administration & dosage] [adverse effects] [therapeutic use];Neuropsychological Tests;Piperidines [administration & dosage] [adverse effects] [therapeutic use];Child[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1089/cap.2010.0024

AB: OBJECTIVE: There has been recent interest in the use of cognitive enhancing drugs, such as cholinesterase inhibitors, as a possible treatment for executive functioning (EF) deficits in autism spectrum disorder (ASD). The goal of this study was to assess the tolerability, safety, and efficacy of donepezil on EF in a sample of children and adolescents with ASD. METHOD: Thirty-four children and adolescents with ASD (age range 8-17 years; IQ >75) were enrolled in a 10-week, double-blind, placebo-controlled trial of donepezil (doses of 5 and 10 mg), followed by a 10-week open label trial for placebo nonresponders. RESULTS: The effect of donepezil treatment on EF was examined. Despite improvement on a number of EF measures, no statistically significant between-group differences were found (with gains observed for both the placebo and donepezil groups). CONCLUSIONS: The results suggest that short-term treatment with donepezil may have limited impact on cognitive functioning in ASD. Future controlled trials may need to consider a longer treatment period to detect significant gains on EF measures.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/697/CN-00787697/frame.html>

Record #128 of 370



ID: CN-00843580

AU: Ginani GE

AU: Tufik S

AU: Bueno OF

AU: Pradella-Hallinan M

AU: Rusted J

AU: Pompéia S

TI: Acute effects of donepezil in healthy young adults underline the fractionation of executive functioning.

SO: Journal of psychopharmacology (Oxford, England)

YR: 2011

VL: 25

NO: 11

PG: 1508-16

PM: PUBMED 21262858

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adolescent;Attention [drug effects];Dose-Response Relationship, Drug;Double-Blind Method;Executive Function [drug effects];Indans [pharmacology];Memory, Short-Term [drug effects];Neuropsychological Tests;Piperidines [pharmacology];Psychomotor Performance [drug effects];Reaction Time [drug effects];Adult[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

DOI: 10.1177/0269881110391832

AB: The cholinergic system is involved in the modulation of both bottom-up and top-down attentional control. Top-down attention engages multiple executive control processes, but few studies have investigated whether all or selective elements of executive functions are modulated by the cholinergic system. To investigate the acute effects of the pro-cholinergic donepezil in young, healthy volunteers on distinct components of executive functions we conducted a double-blind, placebo-controlled, independent-groups design study including 42 young healthy male participants who were randomly assigned to one of three oral treatments: glucose (placebo), donepezil 5 mg or donepezil 7.5 mg. The test battery included measures of different executive components (shifting, updating, inhibition, dual-task performance, planning, access to long-term memory), tasks that evaluated arousal/vigilance/visuomotor performance, as well as functioning of working memory subsidiary systems. Donepezil improved sustained attention, reaction times, dual-task performance and the executive component of digit span. The positive effects in these executive tasks did not correlate with arousal/visuomotor/vigilance measures. Among the various executive domains investigated donepezil selectively increased dual-task performance in a manner that could not be ascribed to improvement in arousal/vigilance/visuomotor performance nor working memory slave systems. Other executive tasks that rely heavily on visuospatial processing may also be modulated by the cholinergic system.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/580/CN-00843580/frame.html>

Record #129 of 370



ID: CN-00804707

AU: Marcantonio ER

AU: Palihnich K

AU: Appleton P

AU: Davis RB

TI: Pilot randomized trial of donepezil hydrochloride for delirium after hip fracture.

SO: Journal of the American Geriatrics Society

YR: 2011

VL: 59 Suppl 2

PG: S282-8

PM: PUBMED 22091574

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Cholinesterase Inhibitors [therapeutic use];Delirium [drug therapy];Double-Blind Method;Hip Fractures [surgery];Indans [therapeutic use];Pilot Projects;Piperidines [therapeutic use];Postoperative Complications [drug therapy];Prospective Studies;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1111/j.1532-5415.2011.03691.x

AB: OBJECTIVES: To determine whether donepezil hydrochloride can reduce the prevalence and severity of delirium in older adults undergoing hip fracture repair. DESIGN: Pilot double-masked randomized placebo-controlled trial. SETTING: Large academic medical center. PARTICIPANTS: Sixteen individuals aged 70 and older with hip fracture. INTERVENTION: Donepezil 5 mg or placebo was randomly allocated and initiated within 24 hours of surgery, preoperatively or postoperatively. Daily treatment was continued for 30 days or until side effects or the clinical situation required termination. MEASUREMENTS: All outcomes were ascertained masked to treatment status. Information on drug tolerability and safety was obtained from the participant, nurse, and medical record. Delirium presence and severity were measured during daily hospital interviews and at 2, 4, and 6 weeks after surgery after a standardized assessment using the Confusion Assessment Method (CAM) and the Memorial Delirium Assessment Scale (MDAS). RESULTS: Participants in the donepezil and placebo arms had similar baseline characteristics. Participants in the donepezil arm experienced significantly more side effects. In longitudinal models, there were no significant differences between the donepezil and placebo arms with regard to delirium presence over time (odds ratio = 0.9, 95% confidence interval (CI) = 0.4-2.3) or delirium severity over time (effect size = -0.2 on 30-point MDAS scale, 95%CI = -1.5-1.2). CONCLUSION: Participants randomized to donepezil had no significant improvement in delirium presence or severity but experienced more side effects. Overall, sufficient evidence was not found from this pilot study to warrant a definitive Phase III trial.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/707/CN-00804707/frame.html>



ID: CN-00780873

AU: Na HR

AU: Kim S

AU: Choi SH

AU: Yang DW

AU: Bae HJ

AU: Kim JE

AU: Park MY

AU: Shim YS

AU: Kim BK

AU: Kwon JC

AU: Yoo BG

AU: Kim BC

AU: Lee JS

TI: Donepezil treatment in Alzheimer's disease patients with and without cerebrovascular lesions: a preliminary report.

SO: Geriatrics & gerontology international

YR: 2011

VL: 11

NO: 1

PG: 90-7

PM: PUBMED 20825496

PT: Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Alzheimer Disease [complications] [drug therapy];Brain [pathology];Cerebrovascular Disorders [complications] [diagnosis];Cholinesterase Inhibitors [administration & dosage] [therapeutic use];Dose-Response Relationship, Drug;Follow-Up Studies;Indans [administration & dosage] [therapeutic use];Magnetic Resonance Imaging;Piperidines [administration & dosage] [therapeutic use];Retrospective Studies;Time Factors;Treatment Outcome;Aged[checkword];Aged, 80 and

over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1111/j.1447-0594.2010.00649.x

AB: AIM: Donepezil has not been evaluated in Korean patients with Alzheimer's disease (AD) for up to 1 year. The objectives of this study were to evaluate the differential efficacy of donepezil in Korean AD patients with and without concomitant cerebrovascular lesions (CVL). METHODS: This study was a 48-week open-label trial of donepezil in patients with probable AD of mild to moderate severity. CVL were evaluated through magnetic resonance imaging (MRI) findings within 3 months. Efficacy analyses were performed for cognitive, behavioral and functional outcome measures. RESULTS: Concomitant CVL were documented in 35 (30.7%) of the patients on MRI. Seventy-nine (69.3%) of the patients were considered not to have concomitant CVL. The mean Mini-Mental State Examination scores of both patients with and without CVL showed improvement at each evaluation. However, there was no statistical difference in improvement between the groups. CONCLUSION: The presence of CVL should not deter clinicians from treating AD with donepezil.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/873/CN-00780873/frame.html>

Record #131 of 370 

ID: CN-00806256

AU: Rapoport MJ

AU: Weaver B

AU: Kiss A

AU: Zuccherò Sarracini C

AU: Møller H

AU: Herrmann N

AU: Lanctôt K

AU: Murray B

AU: Bédard M

TI: The effects of donepezil on computer-simulated driving ability among healthy older adults: a pilot study.

SO: Journal of clinical psychopharmacology

YR: 2011

VL: 31

NO: 5

PG: 587-92

PM: PUBMED 21869695

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Attention [drug effects];Automobile Driving;Cognition [drug effects];Double-Blind Method;Indans [pharmacology];Nootropic Agents [pharmacology];Pilot Projects;Piperidines [pharmacology];Reaction Time [drug effects];User-Computer Interface;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1097/JCP.0b013e31822bb1ba

AB: The purpose of the present pilot study was to examine the effect of donepezil on simulated driving among healthy older adults. Twenty participants with a mean age of 72 years were randomized to take 5 mg of donepezil or placebo for 2 weeks. All participants were assessed at baseline and 2 weeks later on measures of attention, global cognition, and simulated driving on the York driving simulator. Driving measures included speed deviation, deviation of road position, reaction time to wind gusts, and collisions. Groups were compared using analysis of covariance, controlling for baseline values. There were no differences between the groups on attentional measures, number of collisions, or composite simulator measures. The placebo group fared approximately 0.5 second better in reaction time to wind gusts and showed a nonsignificant tendency toward less deviation of road position, compared with the donepezil group. This analysis does not support the use of donepezil to extend the period of safe driving among older adults, but further study is needed regarding its role among patients with cognitive disorders.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/256/CN-00806256/frame.html>

Record #132 of 370



ID: CN-00814300

AU: Balsters JH

AU: O'Connell RG

AU: Martin MP

AU: Galli A

AU: Cassidy SM

AU: Kilcullen SM

AU: Delmonte S

AU: Brennan S

AU: Meaney JF

AU: Fagan AJ

AU: Bokde AL

AU: Upton N

AU: Lai R

AU: Laruelle M

AU: Lawlor B

AU: Robertson IH

TI: Donepezil impairs memory in healthy older subjects: behavioural, EEG and simultaneous EEG/fMRI biomarkers.

SO: PloS one

YR: 2011

VL: 6

NO: 9

PG: e24126

PM: PUBMED 21931653

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Analysis of Variance;Cholinesterase Inhibitors [adverse effects] [pharmacology];Cognition [drug effects] [physiology];Cross-Over Studies;Diarrhea [chemically induced];Double-Blind Method;Electroencephalography [methods];Hippocampus [drug effects] [physiology];Indans [adverse effects] [pharmacology];Magnetic Resonance Imaging [methods];Memory [drug effects] [physiology];Nausea [chemically induced];Piperidines [adverse effects] [pharmacology];Vomiting [chemically induced];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1371/journal.pone.0024126

AB: Rising life expectancies coupled with an increasing awareness of age-related cognitive decline have led to the unwarranted use of psychopharmaceuticals, including acetylcholinesterase inhibitors (AChEIs), by significant numbers of healthy older individuals. This trend has developed despite very limited data regarding the effectiveness of such drugs on non-clinical groups and recent work indicates that AChEIs can have negative cognitive effects in healthy populations. For the first time, we use a combination of EEG and simultaneous EEG/fMRI to examine the effects of a commonly prescribed AChEI (donepezil) on cognition in healthy older participants. The short- and long-term impact of donepezil was assessed using two double-blind, placebo-controlled trials. In both cases, we utilised cognitive (paired associates learning (CPAL)) and electrophysiological measures (resting EEG power) that have demonstrated high-sensitivity to age-related cognitive decline. Experiment 1 tested the effects of 5 mg/per day dosage on cognitive and EEG markers at 6-hour, 2-week and 4-week follow-ups. In experiment 2, the same markers were further scrutinised using simultaneous EEG/fMRI after a single 5 mg dose. Experiment 1 found significant negative effects of donepezil on CPAL and resting Alpha and Beta band power. Experiment 2 replicated these results and found additional drug-related increases in the Delta band. EEG/fMRI analyses revealed that these oscillatory differences were associated with activity differences in the left hippocampus (Delta), right frontal-parietal network (Alpha), and default-mode network (Beta). We demonstrate the utility of simple cognitive and EEG measures in evaluating drug responses after acute and chronic donepezil administration. The presentation of previously established markers of age-related cognitive decline indicates that AChEIs can impair cognitive function in healthy older individuals. To our knowledge this is the first study to identify the precise neuroanatomical origins of EEG drug markers using simultaneous EEG/fMRI. The results of this study may be useful for evaluating novel drugs for cognitive enhancement.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/300/CN-00814300/frame.html>

Record #133 of 370



ID: CN-00842971

AU: Dodds CM

AU: Bullmore ET

AU: Henson RN

AU: Christensen S

AU: Miller S

AU: Smith M

AU: Dewit O

AU: Lawrence P

AU: Nathan PJ

TI: Effects of donepezil on cognitive performance after sleep deprivation.

SO: Human psychopharmacology

YR: 2011

VL: 26

NO: 8

PG: 578-87

PM: PUBMED 22161694

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cognition [drug effects] [physiology];Double-Blind Method;Indans [pharmacology] [therapeutic use];Piperidines [pharmacology] [therapeutic use];Psychomotor Performance [drug effects] [physiology];Reaction Time [drug effects] [physiology];Sleep Deprivation [complications] [drug therapy] [psychology];Treatment Outcome;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1002/hup.1248

AB: OBJECTIVES: To identify tasks that were sensitive to a temporary decline in cognitive performance after sleep deprivation and to investigate the ability of the acetylcholinesterase inhibitor donepezil to reverse any sleep deprivation-induced impairment. METHODS: Thirty healthy volunteers were administered either a 5-mg daily dose of donepezil or placebo for 14-17 days, in a double-blind parallel group design, then underwent either 24h sleep deprivation or a normal night of sleep in non-blinded crossover, and were subsequently tested on a battery of cognitive tasks designed to measure different components of memory and executive function. RESULTS: Sleep deprivation selectively impaired performance on several memory tasks whilst also impairing non-memory function on these tasks. Performance on other tasks was spared. Despite partially reversing the decline in subjective alertness associated with sleep deprivation, treatment with donepezil failed to significantly reverse the decline in cognitive performance on any of the tasks. CONCLUSIONS: The results demonstrate the sensitivity of certain tests, particularly those that measure memory function, to cognitive impairment after sleep deprivation. The inability of donepezil to reverse this performance decline suggests that the sleep deprivation model of cognitive impairment may not be suitable for detecting pro-cognitive effects of cholinergic augmentation.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/971/CN-00842971/frame.html>

Record #134 of 370



ID: CN-00843554

AU: Carrasco MM

AU: Agüera L

AU: Gil P

AU: Moríñigo A

AU: Leon T

TI: Safety and effectiveness of donepezil on behavioral symptoms in patients with Alzheimer disease.

SO: Alzheimer disease and associated disorders

YR: 2011

VL: 25

NO: 4

PG: 333-40

PM: PUBMED 21399485

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Akathisia, Drug-Induced [epidemiology];Alzheimer Disease [drug therapy] [psychology];Diarrhea [chemically induced] [epidemiology];Follow-Up Studies;Indans [adverse effects] [therapeutic use];Piperidines [adverse effects] [therapeutic use];Prospective Studies;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1097/WAD.0b013e318212ab7a

AB: The objective of this study was to evaluate the prevalence and treatment responsiveness of neuropsychiatric symptoms in patients with mild to moderately severe Alzheimer disease recruited in a naturalistic treatment setting in Spain. All the patients, who matched the prescribing recommendations for donepezil and were able to participate in the study, received donepezil (5 to 10 mg/d) for 6 months. The primary outcome measure was the incidence of adverse events. Secondary outcome measures were neuropsychiatric function measured by the Neuropsychiatric Inventory (NPI), the Mini-Mental State Evaluation, and caregiver burden measured by the Zarit scale. Five hundred and twenty-nine patients were included of which

455 completed the study. The mean baseline NPI score was 19.1. Sixty-five patients (12.3%) experienced an adverse event. The most frequent adverse events were diarrhea and agitation (<2%). Seventeen patients (3%) presented with a neuropsychiatric adverse event and 11 (2%) patients presented with a neurologic adverse event over the course of the study. NPI scores improved by 34.4% over the course of the study, with all items showing a statistically significant improvement. Mini-Mental State Evaluation scores and Zarit caregiver burden scores also improved by 1.27 points and 5.9 points, respectively. This study showed a low incidence of adverse events accompanied by an improvement in the neuropsychiatric and cognitive functions in patients with mild to moderately severe Alzheimer disease treated with donepezil in a community setting in Spain. Donepezil also reduced caregiver burden.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/554/CN-00843554/frame.html>

Record #135 of 370



ID: CN-00787261

AU: Burns A

AU: Perry E

AU: Holmes C

AU: Francis P

AU: Morris J

AU: Howes MJ

AU: Chazot P

AU: Lees G

AU: Ballard C

TI: A double-blind placebo-controlled randomized trial of Melissa officinalis oil and donepezil for the treatment of agitation in Alzheimer's disease.

SO: Dementia and geriatric cognitive disorders

YR: 2011

VL: 31

NO: 2

PG: 158-64

PM: PUBMED 21335973

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [psychology];Aromatherapy [adverse effects];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Data Interpretation, Statistical;Double-Blind Method;Indans [adverse effects] [therapeutic use];Melissa [adverse effects] [chemistry];Nootropic Agents [adverse effects] [therapeutic use];Patient Compliance;Piperidines [adverse effects] [therapeutic use];Plant Oils [adverse effects] [therapeutic use];Psychomotor Agitation [drug therapy] [psychology];Quality of Life;Sample Size;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-COMP MED

DOI: 10.1159/000324438

AB: BACKGROUND/AIMS: Behavioural and psychological symptoms (BPSD) are frequent in people with Alzheimer's disease and cause considerable stress to patients and their carers. Antipsychotics have been widely used as a first-line treatment, resulting in an estimated 1,800 excess strokes and 1,600 excess deaths in the UK alone. Safe and effective alternatives are urgently needed. Based upon preliminary evidence from clinical trials, aromatherapy with melissa oil may be such an alternative, but initial studies have been modest in size, and adequate blinding has been problematic. Our objective was to assess the efficacy of melissa aromatherapy in the treatment of agitation in people with Alzheimer's disease in an adequately powered and robustly blinded randomized controlled trial comparing it with donepezil, an anticholinesterase drug used with some benefit to treat BPSD. **METHODS AND FINDINGS:** The study was a double-blind parallel-group placebo-controlled randomized trial across 3 specialist old age psychiatry centres in England. Participants had probable or possible Alzheimer's disease, were resident in a care home, had clinically significant agitation (defined as a score of 39 or above on the Cohen Mansfield Agitation Inventory) and were free of antipsychotics and/or anticholinesterase for at least 2 weeks. Participants were allocated to 1 of 3 groups: placebo medication and active aromatherapy; active medication and placebo aromatherapy or placebo of both. **MAIN OUTCOME:** The primary outcome measure was reduction in agitation as assessed by the Pittsburgh Agitation Scale (PAS) at 4 weeks. This is an observational scale, and raters were required to wear nose clips to ensure that full blinding was maintained. The PAS, Neuropsychiatric Inventory (NPI; another measure of BPSD) and other outcome measures were completed at baseline, 4-week and 12-week follow-ups. 114 participants were randomized, of whom 94 completed the week 4 assessment and 81 completed the week 12 assessment. Aromatherapy and donepezil were well tolerated. There were no significant differences between aromatherapy, donepezil and placebo at week 4 and week 12, but importantly there were substantial improvements in all 3 groups with an 18% improvement in the PAS and a 37% improvement in the NPI over 12 weeks. **CONCLUSION:** When assessed using a rigorous design which ensures blinding of treatment arms, there is no evidence that melissa aromatherapy is superior to placebo or donepezil, in the treatment of

agitation in people with Alzheimer's disease. However, the sizeable improvement in the placebo group emphasizes the potential non-specific benefits of touch and interaction in the treatment of agitation in people with Alzheimer's disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/261/CN-00787261/frame.html>

Record #136 of 370



ID: CN-00778280

AU: Kondoh T

AU: Kanno A

AU: Itoh H

AU: Nakashima M

AU: Honda R

AU: Kojima M

AU: Noguchi M

AU: Nakane H

AU: Nozaki H

AU: Sasaki H

AU: Nagai T

AU: Kosaki R

AU: Kakee N

AU: Okuyama T

AU: Fukuda M

AU: Ikeda M

AU: Shibata Y

AU: Moriuchi H

TI: Donepezil significantly improves abilities in daily lives of female Down syndrome patients with severe cognitive impairment: a 24-week randomized, double-blind, placebo-controlled trial.

SO: International journal of psychiatry in medicine

YR: 2011

VL: 41

NO: 1

PG: 71-89

PM: PUBMED 21495523

PT: Journal Article; Randomized Controlled Trial

KY: Activities of Daily Living;Cognition Disorders [complications] [drug therapy];Double-Blind Method;Down Syndrome [complications] [drug therapy];Indans [therapeutic use];Neuropsychological Tests;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Quality of Life;Treatment Outcome;Adult[checkword];Female[checkword];Humans[checkword];Middle Aged[checkword]

AB: OBJECTIVE: Down syndrome (DS) patients share certain neuropathological features with Alzheimer disease patients. A randomized, double-blind, placebo-controlled study was performed to investigate the efficacy and safety of donepezil, an Alzheimer disease drug, for DS patients. METHOD: Twenty-one DS patients with severe cognitive impairment were assigned to take donepezil (3 mg daily) or a placebo for 24 weeks, and evaluated for activities in daily lives by concisely modified International Classification of Functioning, Disability and Health (ICF) scaling system. RESULTS: ICF scores significantly increased without any adverse effects in the donepezil group in comparison to those in the placebo control. Among the individual functions tested, there was a dramatic improvement in the global mental functions and in specific mental functions. CONCLUSIONS: Donepezil may effectively and safely improve overall functioning of DS patients with severe cognitive impairment.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/280/CN-00778280/frame.html>

Record #137 of 370



ID: CN-00811273

AU: Alvarez XA

AU: Cacabelos R

AU: Sampedro C

AU: Couceiro V

AU: Aleixandre M

AU: Vargas M

AU: Linares C

AU: Granizo E

AU: García-Fantini M

AU: Baurecht W

AU: Doppler E

AU: Moessler H

TI: Combination treatment in Alzheimer's disease: results of a randomized, controlled trial with cerebrolysin and donepezil.

SO: Current Alzheimer research

YR: 2011

VL: 8

NO: 5

PG: 583-91

PM: PUBMED 21679156

PT: Clinical Trial, Phase II; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [drug therapy];Amino Acids [administration & dosage];Double-Blind Method;Indans [administration & dosage];Neuroprotective Agents [administration & dosage];Neuropsychological Tests;Piperidines [administration & dosage];Treatment Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

AB: Treatment with neurotrophic agents might enhance and/or prolong the effects of cholinesterase inhibitors (ChEIs) in Alzheimer's disease (AD). We compared the safety and efficacy of the neurotrophic compound Cerebrolysin (10 ml; n=64), donepezil (10 mg; n=66) and a combination of both treatments (n=67) in mild-to-moderate (mini-mental state examination-MMSE score 12-25) probable AD patients enrolled in a randomized, double-blind trial. Primary endpoints were global outcome (Clinician's Interview-Based Impression of Change plus caregiver input; CIBIC+) and cognition (change from baseline in AD Assessment Scale-cognitive subscale+; ADAS-cog+) at week 28. Changes in functioning (AD Cooperative

Study-Activities of Daily Living scale, ADCS-ADL) and behaviour (Neuropsychiatric Inventory, NPI) were secondary endpoints. Treatment effects in cognitive, functional and behavioral domains showed no significant group differences; whereas improvements in global outcome favored Cerebrolysin and the combination therapy. Cognitive performance improved in all treatment groups (mean±SD for Cerebrolysin: -1.7±7.5; donepezil: -1.2±6.1; combination: -2.3±6.0) with best scores in the combined therapy group at all study visits. Cerebrolysin was as effective as donepezil, and the combination of neurotrophic (Cerebrolysin) and cholinergic (donepezil) treatment was safe in mild-to-moderate AD. The convenience of exploring long-term synergistic effects of this combined therapy is suggested.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/273/CN-00811273/frame.html>

Record #138 of 370



ID: CN-00811031

AU: Chang WH

AU: Park YH

AU: Ohn SH

AU: Park CH

AU: Lee PK

AU: Kim YH

TI: Neural correlates of donepezil-induced cognitive improvement in patients with right hemisphere stroke: a pilot study.

SO: Neuropsychological rehabilitation

YR: 2011

VL: 21

NO: 4

PG: 502-14

PM: PUBMED 21714757

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Brain Mapping [methods] [psychology];Cognition Disorders [complications] [drug therapy] [physiopathology];Functional Laterality [physiology];Indans [therapeutic use];Neural Pathways

[drug effects] [physiopathology];Neuropsychological Tests [statistics & numerical data];Nootropic Agents [therapeutic use];Pilot Projects;Piperidines [therapeutic use];Stroke [complications] [drug therapy] [physiopathology];Adult[checkword];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1080/09602011.2011.582708

AB: Donepezil has been proven effective in the treatment of Alzheimer's disease and vascular dementia. However, its effects on the cognitive neural network have not been fully investigated. The purpose of this study was to evaluate the effect of donepezil on reorganisation of the cognitive neural network in patients with post-stroke cognitive impairment using functional MRI (fMRI). Fourteen patients with stroke in the right hemisphere were enrolled. Participants were randomly assigned to the experimental or the control group. Donepezil (5 mg) or placebo was administered daily for four weeks. Cognitive function assessment was performed before and immediately after treatment, and repeated one month after cessation of treatment. fMRI was performed before and after treatment. Ten out of 14 patients (six in the experimental group, four in the control group) successfully completed all experimental processes. The experimental group showed significant improvements in the Mini-Mental Status Examination during the post-treatment evaluation and one-month follow-up compared to the pre-treatment evaluation ($p < .05$). No improvement was observed in the control group. In the experimental group fMRI showed increased activation in both prefrontal areas, both inferior frontal lobes, and in the left inferior parietal lobe. Increased recruitment of the parieto-frontal networks in the selected patients was considered to be a neural correlate of cognitive improvement induced by donepezil.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/031/CN-00811031/frame.html>

Record #139 of 370



ID: CN-00843621

AU: Schuff N

AU: Suhy J

AU: Goldman R

AU: Xu Y

AU: Sun Y

AU: Truran-Sacrey D

AU: Murthy A

TI: An MRI substudy of a donepezil clinical trial in mild cognitive impairment.

SO: Neurobiology of aging

YR: 2011

VL: 32

NO: 12

PG: 2318.e31-41

PM: PUBMED 20541841

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Brain [drug effects] [pathology];Double-Blind Method;Indans [pharmacology] [therapeutic use];Magnetic Resonance Imaging [methods];Mild Cognitive Impairment [diagnosis] [drug therapy] [psychology];Piperidines [pharmacology] [therapeutic use];Single-Blind Method;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1016/j.neurobiolaging.2010.04.005

AB: A magnetic resonance imaging (MRI) study was conducted as part of an intervention study in subjects with amnesic mild cognitive impairment (aMCI) to assess donepezil's treatment effect on brain atrophy. Adults with aMCI were randomly assigned to double-blind treatment with 10 mg/day donepezil hydrochloride or placebo for 48 weeks. Brain MRI scans were acquired at baseline and endpoint. The primary outcome measure was annualized percentage change (APC) in hippocampal volume; the main secondary outcome measure was APC in whole brain volumes. An analysis of variance (ANOVA) model including terms for treatment, site, and age was used to compare the treatment groups. APCs for hippocampal volumes were not significantly different between treatment groups. There were significant differences favoring the donepezil group for total ($p = 0.001$), ventricular region ($p = 0.0002$), and cortical region ($p = 0.003$) whole brain volumes. Although the primary MRI outcome measure was negative, the main secondary MRI outcome measure showed a positive result. These findings suggest a treatment effect of donepezil on brain atrophy in aMCI.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/621/CN-00843621/frame.html>

Record #140 of 370



ID: CN-00890090

AU: Goveas JS

AU: Xie C

AU: Ward BD

AU: Wu Z

AU: Li W

AU: Franczak M

AU: Jones JL

AU: Antuono PG

AU: Li S-J

TI: Recovery of hippocampal network connectivity correlates with cognitive improvement in mild Alzheimer's disease patients treated with donepezil assessed by resting-state fMRI.

SO: Journal of magnetic resonance imaging

YR: 2011

VL: 34

NO: 4

PG: 764-73

XR: EMBASE 2011526875

PT: Journal: Article


KY: aged // *Alzheimer disease/dt [Drug Therapy] // Alzheimer Disease Assessment Scale // article // behavior change // cholinergic system // clinical article // *cognition // controlled clinical trial // controlled study // convalescence // drug dose increase // female // functional assessment // *functional magnetic resonance imaging // *hippocampus // *hippocampus functional connectivity // human // inferior frontal gyrus // Instrumental Activities of Daily Living scale // left hemisphere // male // Mini Mental State Examination // neuroimaging // neuropsychiatric inventory // neuropsychological test // parahippocampal gyrus // prefrontal cortex // priority journal // rating scale // rest // temporal lobe // treatment outcome // treatment response // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy]

DOI: 10.1002/jmri.22662

AB: Purpose: To identify the neural correlates of cognitive improvement in mild Alzheimer's disease (AD) subjects following 12 weeks of donepezil treatment. Materials and Methods: Resting-state functional connectivity magnetic resonance imaging (R-fMRI) was used to measure the hippocampal functional connectivity (HFC) in 14 mild AD and 18 age-matched normal (CN) subjects. AD subjects were scanned at baseline and after donepezil treatment. CN

subjects were scanned only at baseline as a reference to identify regions correlated or anticorrelated to the hippocampus. Before each scan, participants underwent cognitive, behavioral, and functional assessments. Results: After donepezil treatment, neural correlates of cognitive improvement measured by Mini-Mental State Examination scores were identified in the left parahippocampus, dorsolateral prefrontal cortex (DLPFC), and inferior frontal gyrus. Improvement in AD Assessment Scale-cognitive subscale scores correlated with the HFC changes in the left DLPFC and middle frontal gyrus. Stronger recovery in the network connectivity was associated with cognitive improvement. Conclusion: R-fMRI may provide novel insights into the brain's responses to AD treatment in clinical pharmacological trials, and also may predict clinical response. Copyright 2011 Wiley-Liss, Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/090/CN-00890090/frame.html>

Record #141 of 370 

ID: CN-00843484

AU: Cho W

AU: Maruff P

AU: Connell J

AU: Gargano C

AU: Calder N

AU: Doran S

AU: Fox-Bosetti S

AU: Hassan A

AU: Renger J

AU: Herman G

AU: Lines C

AU: Verma A

TI: Additive effects of a cholinesterase inhibitor and a histamine inverse agonist on scopolamine deficits in humans.

SO: Psychopharmacology

YR: 2011

VL: 218

NO: 3

PG: 513-24

PM: PUBMED 21644059

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Area Under Curve;Cholinergic Antagonists [adverse effects];Cholinesterase Inhibitors [administration & dosage] [pharmacology];Cognition [drug effects];Cross-Over Studies;Double-Blind Method;Drug Inverse Agonism;Drug Therapy, Combination;Histamine Agonists [administration & dosage] [pharmacology];Indans [administration & dosage] [pharmacology];Maze Learning [drug effects];Piperidines [administration & dosage] [pharmacology];Receptors, Histamine H3 [drug effects] [metabolism];Scopolamine Hydrobromide [adverse effects];Adult[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

DOI: 10.1007/s00213-011-2344-y

AB: RATIONALE: Enhancement of histaminergic neurotransmission or histaminergic plus cholinergic neurotransmission may represent novel strategies for improving cognition in Alzheimer's disease. OBJECTIVE: To evaluate the effects of a novel histamine H3 receptor inverse agonist (MK-3134), an acetylcholinesterase inhibitor (donepezil), and their combination in attenuating the cognitive impairment associated with scopolamine. METHODS: Thirty-one subjects were randomized, and 28 completed this double-blind, placebo-controlled, five-period crossover study. Cognition was assessed using the Groton Maze Learning Task (GMLT) as the primary outcome measure. The two primary hypotheses were that donepezil 10 mg and MK-3134 25 mg, respectively, would attenuate scopolamine (0.5 mg)-induced impairment as measured by the GMLT over the first 12 h after scopolamine administration (AUC(1-12) h). A secondary hypothesis was that the combination of donepezil and MK-3134 would attenuate scopolamine-induced cognitive impairment to a greater extent than either agent alone as measured by the GMLT AUC(1-12 h). RESULTS: The primary and secondary hypotheses were not met. Upon examining the time course of the scopolamine effects (an exploratory objective), peak effects were generally observed around 2 h after scopolamine administration. Administration of MK-3134 or donepezil improved performance on the GMLT at the 2-h time point, rather than AUC(1-12 h), compared with scopolamine alone. Moreover, it appeared that the combination of MK-3134 and donepezil blunted the scopolamine effect to a greater extent than either drug alone. CONCLUSIONS: Exploratory analyses provide evidence for cognitive improvement through inverse agonism of the H3 histamine receptor and for cooperation between human cholinergic and histaminergic neurotransmitter systems. (ClinicalTrials.gov trial registration number: NCT01181310).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/484/CN-00843484/frame.html>

Record #142 of 370



ID: CN-00863775

AU: Doody RS

AU: Ramos H

AU: Faison W

AU: Zou H

TI: Efficacy and Safety of Donepezil 23 mg/d vs. Donepezil 10 mg/d in Patients with Moderate to Severe Alzheimer's Disease: Impact of Concomitant Memantine Use

SO: Journal of the American Geriatrics Society

YR: 2011

VL: Conference: 2011 Annual Scientific Meeting of the American Geriatrics Society National Harbor, MD United States. Conference Start: 20110511 Conference End: 20110514.

NO: var.pagings

PG: S30

XR: EMBASE 70989714

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/775/CN-00863775/frame.html>

Record #143 of 370



ID: CN-00894985

AU: Frolich L

AU: Ashwood T

AU: Nilsson J

AU: Eckerwall G

TI: Effects of AZD3480 on cognition in patients with mild-to-moderate alzheimer's disease: A phase IIb dose-finding study.

SO: Journal of Alzheimer's disease

YR: 2011

VL: 24

NO: 2

PG: 363-74

XR: EMBASE 2011242417

PT: Journal: Article


KY: AD Assessment Scale cognitive subscale // ad cooperative study clinical global impression of change // adult // aged // *Alzheimer disease/dt [Drug Therapy] // anxiety // arthralgia/si [Side Effect] // article // backache/si [Side Effect] // blood pressure // clinical assessment tool // *cognition // controlled study // diarrhea/si [Side Effect] // disability assessment for dementia // disease severity // dizziness/si [Side Effect] // dose response // double blind procedure // drug dose increase // drug effect // drug efficacy // drug safety // drug tolerability // drug withdrawal // evening dosage // fatigue/si [Side Effect] // female // headache/si [Side Effect] // human // influenza/si [Side Effect] // insomnia/si [Side Effect] // major clinical study // male // Mini Mental State Examination // morning dosage // multicenter study // nausea/si [Side Effect] // nightmare/si [Side Effect] // outcome assessment // patient compliance // peripheral edema/si [Side Effect] // phase 2 clinical trial // priority journal // randomized controlled trial // rhinopharyngitis/si [Side Effect] // side effect/si [Side Effect] // treatment duration // treatment refusal // treatment withdrawal // urinary tract infection/si [Side Effect] // urine incontinence/si [Side Effect] // vomiting/si [Side Effect] // withdrawal syndrome/si [Side Effect] // donepezil/ae [Adverse Drug Reaction] // donepezil/cm [Drug Comparison] // donepezil/dt [Drug Therapy] // *ispronicline/ae [Adverse Drug Reaction] // *ispronicline/ct [Clinical Trial] // *ispronicline/cm [Drug Comparison] // *ispronicline/do [Drug Dose] // *ispronicline/dt [Drug Therapy] // placebo

DOI: 10.3233/JAD-2011-101554

AB: AZD3480 is a selective agonist of the central alpha4beta2 and alpha2beta2 neuronal nicotinic cholinergic receptors (NNRs). Its effects on cognition were investigated in 567 patients with mild-to-moderate Alzheimer's disease (AD) (Mini Mental State Examination [MMSE] 12-26). Mean baseline MMSE was 21 (SD + 3.7), with 61% of patients having mild disease (MMSE 21-26). Mean age was 74 (range 58-85) years. Patients were randomized to one of 5 treatment groups: AZD3480 5 mg, 20 mg or 35/100 mg, donepezil 10 mg (active comparator) or placebo, and treated once daily for 12 weeks. The primary outcome measure was change from baseline at Week 12 on the AD Assessment Scale-Cognitive Subscale (ADAS-Cog). Neither AZD3480 nor donepezil showed a statistically significant improvement versus placebo on ADAS-Cog. Improvements in a number of secondary outcome measures (MMSE, AD Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) and Disability Assessment for Dementia [DAD]) were observed for AZD3480 and for donepezil. A post-hoc analysis on ADAS-Cog, excluding patients with very mild AD (MMSE 25-26) indicated

improvement versus placebo for AZD3480 20 mg (-1.4, 95% CI:-3.0; 0.2) and donepezil (-1.0, 95% CI:-2.3; 0.3). AZD3480 was well tolerated. The study did not meet proof of concept criteria: since neither AZD3480 nor donepezil were statistically significantly superior to placebo on ADAS-Cog and was considered to be inconclusive. Further studies are required to determine the therapeutic potential of stimulating alpha4beta2 receptors with NNRs in AD patients. 2011 - IOS Press and the authors. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/985/CN-00894985/frame.html>

Record #144 of 370 

ID: CN-00784954

AU: Frölich L

AU: Ashwood T

AU: Nilsson J

AU: Eckerwall G

TI: Effects of AZD3480 on cognition in patients with mild-to-moderate Alzheimer's disease: a phase IIb dose-finding study.

SO: Journal of Alzheimer's disease

YR: 2011

VL: 24

NO: 2

PG: 363-74

PM: PUBMED 21258153

PT: Clinical Trial, Phase II; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [complications];Cholinesterase Inhibitors [therapeutic use];Cognition Disorders [drug therapy] [etiology];Dose-Response Relationship, Drug;Double-Blind Method;Indans [therapeutic use];Mental Status Schedule;Neuroprotective Agents [therapeutic use];Neuropsychological Tests;Piperidines [therapeutic use];Pyridines [therapeutic use];Time Factors;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.3233/JAD-2011-101554

AB: AZD3480 is a selective agonist of the central $\alpha 4 \beta 2$ and $\alpha 2 \beta 2$ neuronal nicotinic cholinergic receptors (NNRs). Its effects on cognition were investigated in 567 patients with mild-to-moderate Alzheimer's disease (AD) (Mini Mental State Examination [MMSE] 12-26). Mean baseline MMSE was 21 (SD \pm 3.7), with 61% of patients having mild disease (MMSE 21-26). Mean age was 74 (range 58-85) years. Patients were randomized to one of 5 treatment groups: AZD3480 5 mg, 20 mg or 35/100 mg, donepezil 10 mg (active comparator) or placebo, and treated once daily for 12 weeks. The primary outcome measure was change from baseline at Week 12 on the AD Assessment Scale-Cognitive Subscale (ADAS-Cog). Neither AZD3480 nor donepezil showed a statistically significant improvement versus placebo on ADAS-Cog. Improvements in a number of secondary outcome measures (MMSE, AD Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) and Disability Assessment for Dementia [DAD]) were observed for AZD3480 and for donepezil. A post-hoc analysis on ADAS-Cog, excluding patients with very mild AD (MMSE 25-26) indicated improvement versus placebo for AZD3480 20 mg (-1.4, 95% CI: -3.0; 0.2) and donepezil (-1.0, 95% CI: -2.3; 0.3). AZD3480 was well tolerated. The study did not meet proof of concept criteria: since neither AZD3480 nor donepezil were statistically significantly superior to placebo on ADAS-Cog and was considered to be inconclusive. Further studies are required to determine the therapeutic potential of stimulating $\alpha 4 \beta 2$ receptors with NNRs in AD patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/954/CN-00784954/frame.html>

Record #145 of 370



ID: CN-00834131

AU: Sukys-Claudino L

AU: Moraes W

AU: Poyares D

AU: Tufik S

TI: Donepezil improves obstructive sleep apnea and sleepiness [Abstract]

SO: Sleep

YR: 2011

VL: 34

NO: Suppl

PG: A144 [0416]

CC: SR-AIRWAYS

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/131/CN-00834131/frame.html>

Record #146 of 370



ID: CN-00802571

AU: Parnetti L

AU: Chiasserini D

AU: Andreasson U

AU: Ohlson M

AU: Hüls C

AU: Zetterberg H

AU: Minthon L

AU: Wallin AK

AU: Andreasen N

AU: Talesa VN

AU: Blennow K

TI: Changes in CSF acetyl- and butyrylcholinesterase activity after long-term treatment with AChE inhibitors in Alzheimer's disease.

SO: Acta neurologica Scandinavica

YR: 2011

VL: 124

NO: 2

PG: 122-9

PM: PUBMED 20880294

PT: Journal Article; Randomized Controlled Trial

KY: Acetylcholinesterase [blood] [cerebrospinal fluid];Alzheimer Disease [blood] [cerebrospinal fluid] [drug therapy];Amyloid beta-Peptides [cerebrospinal fluid];Butyrylcholinesterase [blood] [cerebrospinal fluid];Cholinesterase Inhibitors [therapeutic use];Double-Blind

Method;Longitudinal Studies;Peptide Fragments [cerebrospinal fluid];Statistics, Nonparametric;tau Proteins [cerebrospinal fluid];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1111/j.1600-0404.2010.01435.x

AB: OBJECTIVES: ? To measure cerebrospinal fluid (CSF) activity of acetylcholinesterase (AChE) and butyrylcholinesterase (BChE) in patients with Alzheimer's disease (AD) participating in randomized clinical trials from three European centers, before and after long-term treatment with different AChE inhibitors (AChEIs). MATERIALS AND METHODS: ? Of the 144 patients included in the study, 104 were treated with donepezil, 15 with galantamine, 16 with rivastigmine, and nine with placebo. CSF AChE and BChE activities were measured at baseline and after 1- year treatment. RESULTS: Donepezil and galantamine groups showed a significant increase in CSF AChE activity at follow-up, while no changes for BChE activity were observed; in donepezil group, a positive correlation between plasma concentration and AChE activity was documented. Conversely, in rivastigmine group, a decrease in CSF activity of both enzymes was observed. CSF AChE and BChE activities were not correlated with the clinical outcome in any group considered. CSF biomarkers did not show any change after treatment. CONCLUSIONS: ? AChEIs differently influence the activity of target enzymes in CSF independent of their pharmacodynamic effects.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/571/CN-00802571/frame.html>

Record #147 of 370



ID: CN-00857003

AU: Burns A

AU: Perry E

AU: Holmes C

AU: Francis P

AU: Morris J

AU: Howes MJR

TI: A double-blind placebo-controlled randomized trial of Melissa officinalis oil and donepezil for the treatment of agitation in Alzheimer's disease

SO: Dementia and geriatric cognitive disorders

YR: 2011

VL: 31

PG: 158-64

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/003/CN-00857003/frame.html>

Record #148 of 370



ID: CN-00799808

AU: Azuara-Blanco A

AU: Burr JM

AU: Cochran C

AU: Ramsay C

AU: Vale L

AU: Foster P

AU: Friedman D

AU: Quayyum Z

AU: Lai J

AU: Nolan W

AU: Aung T

AU: Chew P

AU: McPherson G

AU: McDonald A

AU: Norrie J

TI: The effectiveness of early lens extraction with intraocular lens implantation for the treatment of primary angle-closure glaucoma (EAGLE): study protocol for a randomized controlled trial.

SO: Trials

YR: 2011

VL: 12

PG: 133

PM: PUBMED 21605352

PT: Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Asia;Cost-Benefit Analysis;Glaucoma, Angle-Closure [diagnosis] [economics] [physiopathology] [surgery];Great Britain;Health Care Costs;Intraocular Pressure;Lens Implantation, Intraocular [adverse effects] [economics] [instrumentation];Lens, Crystalline [physiopathology] [surgery];Lenses, Intraocular;Ophthalmic Solutions;Phacoemulsification [adverse effects] [economics];Quality of Life;Questionnaires;Recovery of Function;Research Design;Time Factors;Trabeculectomy;Treatment Outcome;Vision, Ocular;Visual Acuity;Visual Fields;Humans[checkword];Middle Aged[checkword]

DOI: 10.1186/1745-6215-12-133

AB: BACKGROUND: Glaucoma is the leading cause of irreversible blindness. Although primary open-angle glaucoma is more common, primary angle-closure glaucoma (PACG) is more likely to result in irreversible blindness. By 2020, 5.3 million people worldwide will be blind because of PACG. The current standard care for PACG is a stepped approach of a combination of laser iridotomy surgery (to open the drainage angle) and medical treatment (to reduce intraocular pressure). If these treatments fail, glaucoma surgery (eg, trabeculectomy) is indicated. It has been proposed that, because the lens of the eye plays a major role in the mechanisms leading to PACG, early clear lens extraction will improve glaucoma control by opening the drainage angle. This procedure might reduce the need for drugs and glaucoma surgery, maintain good visual acuity, and improve quality of life compared with standard care. EAGLE aims to evaluate whether early lens extraction improves patient-reported, clinical outcomes, and cost-effectiveness, compared with standard care. METHODS/DESIGN: EAGLE is a multicentre pragmatic randomized trial. All people presenting to the recruitment centres in the UK and east Asia with newly diagnosed PACG and who are at least 50 years old are eligible. The primary outcomes are EQ-5D, intraocular pressure, and incremental cost per quality adjusted life year (QALY) gained. Other outcomes are: vision and glaucoma-specific patient-reported outcomes, visual acuity, visual field, angle closure, number of medications, additional surgery (e.g., trabeculectomy), costs to the health services and patients, and adverse events. A single main analysis will be done at the end of the trial, after three years of follow-up. The analysis will be based on all participants as randomized (intention to treat). 400 participants (200 in each group) will be recruited, to have 90% power at 5% significance level to detect a difference in EQ-5D score between the two groups of 0.05, and a mean difference in intraocular pressure of 1.75 mm Hg. The study will have 80% power to detect a difference of 15% in the glaucoma surgery rate. TRIAL REGISTRATION: ISRCTN44464607.

US: <http://onlinelibrary.wiley.com/doi/10.1002/14651909.CD007998>

Record #149 of 370



ID: CN-00888613

AU: Thuiller W

AU: Lavergne S

AU: Roquet C

AU: Boulangeat I

AU: Lafourcade B

AU: Araujo MB

TI: Consequences of climate change on the tree of life in Europe.

SO: Nature

YR: 2011

VL: 470

NO: 7335

PG: 531-4

XR: EMBASE 2011119914

PT: Journal: Article

KY: article // bird // *climate change // Europe // genetic variability // latitude // mammal // nonhuman // phylogenetic tree // plant // priority journal // randomized controlled trial // *tree of life

DOI: 10.1038/nature09705

AB: Many species are projected to become vulnerable to twenty-first-century climate changes, with consequent effects on the tree of life. If losses were not randomly distributed across the tree of life, climate change could lead to a disproportionate loss of evolutionary history. Here we estimate the consequences of climate change on the phylogenetic diversities of plant, bird and mammal assemblages across Europe. Using a consensus across ensembles of forecasts for 2020, 2050 and 2080 and high-resolution phylogenetic trees, we show that species vulnerability to climate change clusters weakly across phylogenies. Such phylogenetic signal in species vulnerabilities does not lead to higher loss of evolutionary history than expected with a model of random extinctions. This is because vulnerable species have neither fewer nor closer relatives than the remaining clades. Reductions in phylogenetic diversity will be greater in southern Europe, and gains are expected in regions of high latitude or altitude. However,

losses will not be offset by gains and the tree of life faces a trend towards homogenization across the continent. 2011 Macmillan Publishers Limited. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/613/CN-00888613/frame.html>

Record #150 of 370



ID: CN-00882483

AU: Kavanagh S

AU: Baelen B

AU: Schäuble B

TI: Long-term effects of galantamine on cognitive function in Alzheimer's disease: a large-scale international retrospective study.

SO: Journal of Alzheimer's disease

YR: 2011

VL: 27

NO: 3

PG: 521-30

PM: PUBMED 21891871

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [epidemiology] [psychology];Brief Psychiatric Rating Scale;Cognition [drug effects] [physiology];Cognition Disorders [drug therapy] [epidemiology] [psychology];Follow-Up Studies;Galantamine [administration & dosage];Internationality;Retrospective Studies;Time Factors;Treatment Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.3233/JAD-2011-110417

AB: In Alzheimer's disease (AD), it is important to consider long-term effects, not only in patients receiving treatment, but also in subjects in whom therapy has been discontinued. The present analysis evaluates the long-term effects of galantamine on cognitive function in AD in terms of Mini-Mental State Examination (MMSE) scores for up to 7 years, using both clinical data and epidemiological modeling. Consideration is given not only to patients continuing to receive galantamine therapy, but also to those who stop this treatment. In a retrospective

review of medical notes, re-contacted study investigators obtained data from 258 patients originally recruited into three previously described randomized clinical trials involving galantamine: two placebo-controlled trials in mild-to-moderate AD (of 3 and 6 months' duration, followed by open-label extensions) and the galantamine-treatment arm of a 12-month comparative study with donepezil in moderate AD. Information relating to disease progression was collated (up to five MMSE scores, separated by at least 3 months, for each patient). Changes in MMSE scores over time were evaluated using observed data. In the absence of long-term placebo, the rate of cognitive decline without treatment was projected using a previously described epidemiological model. A new, exploratory statistical model was also developed. Results showed that patients with mild-to-moderate AD who received long-term galantamine treatment exhibited attenuated decline in cognitive function, as assessed by MMSE, compared with decline predicted in the absence of treatment. Furthermore, patients who stopped treatment experienced subsequent cognitive decline at a rate similar to that predicted for untreated patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/483/CN-00882483/frame.html>

Record #151 of 370



ID: CN-00811706

AU: Harrington C

AU: Sawchak S

AU: Chiang C

AU: Davies J

AU: Donovan C

AU: Saunders AM

AU: Irizarry M

AU: Jeter B

AU: Zvartau-Hind M

AU: Dyck CH

AU: Gold M

TI: Rosiglitazone does not improve cognition or global function when used as adjunctive therapy to AChE inhibitors in mild-to-moderate Alzheimer's disease: two phase 3 studies.

SO: Current Alzheimer research

YR: 2011

VL: 8

NO: 5

PG: 592-606

PM: PUBMED 21592048

PT: Clinical Trial, Phase III; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Chemotherapy, Adjuvant;Cholinesterase Inhibitors [administration & dosage];Double-Blind Method;Hypoglycemic Agents [administration & dosage];Indans [administration & dosage];Neuropsychological Tests;Piperidines [administration & dosage];Thiazolidinediones [administration & dosage];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

AB: INTRODUCTION: Two phase 3 studies evaluated the efficacy and safety of rosiglitazone (RSG), a type 2 diabetes treatment, in an extended release (RSG XR) form as adjunctive therapy to ongoing acetylcholine esterase inhibitor (AChEI) treatment in AD (REFLECT-2, adjunctive to donepezil; REFLECT-3, to any AChEI). An open-label extension study (REFLECT-4) assessed RSG XR long-term safety. METHODS: In these two double-blind, placebo-controlled studies, subjects with mild-to-moderate probable AD were randomized within 2 apolipoprotein E (APOE) allelic strata (APOE ϵ 4-positive, APOE ϵ 4-negative) to once daily placebo, 2 mg RSG XR, or 8 mg RSG XR for 48 weeks (REFLECT-2, N=1,496; REFLECT-3, N=1,485). Co-primary efficacy endpoints were change from baseline in Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog) and Clinical Dementia Rating scale - Sum of Boxes (CDR-SB) scores at week 48. Three populations were analyzed: APOE4-negative, all subjects except APOE ϵ 4 homozygotes, and the full intent-to-treat population. RESULTS: No statistically or clinically relevant differences between treatment groups were observed on the a priori primary endpoints in REFLECT-2 or REFLECT-3. Edema was the most frequent adverse event with RSG in each study (14% and 19%, respectively, at 8 mg RSG XR). CONCLUSIONS: No evidence of statistically or clinically significant efficacy in cognition or global function was detected for 2 mg or 8 mg RSG XR as adjunctive therapy to ongoing AChEIs. There was no evidence of an interaction between treatment and APOE status. Safety and tolerability of RSG XR was consistent with the known profile of rosiglitazone.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/706/CN-00811706/frame.html>

Record #152 of 370



ID: CN-00788595

AU: Atri A

AU: O'Brien JL

AU: Sreenivasan A

AU: Rastegar S

AU: Salisbury S

AU: DeLuca AN

AU: O'Keefe KM

AU: LaViolette PS

AU: Rentz DM

AU: Locascio JJ

AU: Sperling RA

TI: Test-retest reliability of memory task functional magnetic resonance imaging in Alzheimer disease clinical trials.

SO: Archives of neurology

YR: 2011

VL: 68

NO: 5

PG: 599-606

PM: PUBMED 21555634


PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, Non-P.H.S.

KY: Alzheimer Disease [blood] [pathology] [physiopathology] [psychology]; Cognition Disorders [pathology] [physiopathology]; Double-Blind Method; Feasibility Studies; Hippocampus [pathology] [physiopathology]; Magnetic Resonance Imaging; Memory; Memory Disorders [pathology] [physiopathology]; Neuropsychological Tests; Oxygen [blood]; Patient Selection; Reproducibility of Results; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

DOI: 10.1001/archneurol.2011.94

AB: OBJECTIVE: To examine the feasibility and test-retest reliability of encoding-task functional magnetic resonance imaging (fMRI) in mild Alzheimer disease (AD). DESIGN: Randomized, double-blind, placebo-controlled study. SETTING: Memory clinical trials unit. PARTICIPANTS: We studied 12 patients with mild AD (mean [SEM] Mini-Mental State Examination score, 24.0 [0.7]; mean Clinical Dementia Rating score, 1.0) who had been taking donepezil hydrochloride for more than 6 months from the placebo arm of a larger 24-week study (n = 24, 4 scans on weeks 0, 6, 12, and 24, respectively). INTERVENTIONS: Placebo and 3 face-name, paired-associate encoding, block-design blood oxygenation level-dependent fMRI scans in 12 weeks. MAIN OUTCOME MEASURES: We performed whole-brain t maps ($P < .001$, 5 contiguous voxels) and hippocampal regions-of-interest analyses of extent (percentage of active voxels) and magnitude (percentage of signal change) for novel-greater-than-repeated face-name contrasts. We also calculated intraclass correlation coefficients and power estimates for hippocampal regions of interest. RESULTS: Task tolerability and data yield were high (95 of 96 scans yielded favorable-quality data). Whole-brain maps were stable. Right and left hippocampal regions-of-interest intraclass correlation coefficients were 0.59 to 0.87 and 0.67 to 0.74, respectively. To detect 25.0% to 50.0% changes in week-0 to week-12 hippocampal activity using left-right extent or right magnitude with 80.0% power (2-sided $\alpha = .05$) requires 14 to 51 patients. Using left magnitude requires 125 patients because of relatively small signal to variance ratios. CONCLUSIONS: Encoding-task fMRI was successfully implemented in a single-site, 24-week, AD randomized controlled trial. Week 0 to 12 whole-brain t maps were stable, and test-retest reliability of hippocampal fMRI measures ranged from moderate to substantial. Right hippocampal magnitude may be the most promising of these candidate measures in a leveraged context. These initial estimates of test-retest reliability and power justify evaluation of encoding-task fMRI as a potential biomarker for signal of effect in exploratory and proof-of-concept trials in mild AD. Validation of these results with larger sample sizes and assessment in multisite studies is warranted.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/595/CN-00788595/frame.html>

Record #153 of 370 

ID: CN-00894737

AU: Piette F

AU: Belmin J

AU: Vincent H

AU: Schmidt N

AU: Pariel S

AU: Verny M

AU: Marquis C

AU: Mely J

AU: Hugonot-Diener L

AU: Kinet J-P

AU: Dubreuil P

AU: Moussy A

AU: Hermine O

TI: Masitinib as an adjunct therapy for mild-to-moderate Alzheimer's disease: A randomised, placebo-controlled phase 2 trial.

SO: Alzheimer's research & therapy

YR: 2011

VL: 3

NO: 2

XR: EMBASE 2011300018

PT: Journal: Article

KY: add on therapy // aged // *Alzheimer disease/dt [Drug Therapy] // aminotransferase blood level // anorexia/si [Side Effect] // arthralgia/si [Side Effect] // article // assessment scale cognitive subscale // asthenia/si [Side Effect] // balance disorder/si [Side Effect] // bronchitis/si [Side Effect] // clinical article // cognition // controlled study // daily life activity // depression/si [Side Effect] // diarrhea/si [Side Effect] // disease severity // double blind procedure // drug efficacy // drug eruption/si [Side Effect] // eyelid edema/si [Side Effect] // female // gastrointestinal disease/si [Side Effect] // human // leukopenia/si [Side Effect] // male // metabolic disorder/si [Side Effect] // Mini Mental State Examination // multicenter study // neutropenia/si [Side Effect] // phase 2 clinical trial // priority journal // randomized controlled trial // rating scale // scoring system // side effect/si [Side Effect] // vomiting/si [Side Effect] // donepezil/ae [Adverse Drug Reaction] // donepezil/ct [Clinical Trial] // donepezil/cb [Drug Combination] // donepezil/dt [Drug Therapy] // galantamine/ae [Adverse Drug Reaction] // galantamine/ct [Clinical Trial] // galantamine/cb [Drug Combination] // galantamine/dt [Drug Therapy] // *masitinib/ae [Adverse Drug Reaction] // *masitinib/ct [Clinical Trial] // *masitinib/cb [Drug Combination] // *masitinib/dt [Drug Therapy] // memantine/ae [Adverse Drug Reaction] // memantine/ct [Clinical Trial] // memantine/cb [Drug Combination] // memantine/dt [Drug Therapy] // placebo // rivastigmine/ae [Adverse Drug Reaction] // rivastigmine/ct [Clinical Trial] // rivastigmine/cb [Drug Combination] // rivastigmine/dt [Drug Therapy]

DOI: 10.1186/alzrt75

AB: Introduction. Neuroinflammation is thought to be important in Alzheimer's disease pathogenesis. Mast cells are a key component of the inflammatory network and participate in the regulation of the blood-brain barrier's permeability. Masitinib, a selective oral tyrosine kinase inhibitor, effectively inhibits the survival, migration and activity of mast cells. As the brain is rich in mast cells, the therapeutic potential of masitinib as an adjunct therapy to standard care was investigated. Methods. A randomised, placebo-controlled, phase 2 study was performed in patients with mild-to-moderate Alzheimer's disease, receiving masitinib as an adjunct to cholinesterase inhibitor and/or memantine. Patients were randomly assigned to receive masitinib (n = 26) (starting dose of 3 or 6 mg/kg/day) or placebo (n = 8), administered twice daily for 24 weeks. The primary endpoint was change from baseline in the Alzheimer's Disease Assessment Scale - cognitive subscale (ADAS-Cog) to assess cognitive function and the related patient response rate. Results: The rate of clinically relevant cognitive decline according to the ADAS-Cog response (increase >4 points) after 12 and 24 weeks was significantly lower with masitinib adjunctive treatment compared with placebo (6% vs. 50% for both time points; P = 0.040 and P = 0.046, respectively). Moreover, whilst the placebo treatment arm showed worsening mean ADAS-Cog, Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory, and Mini-Mental State Examination scores, the masitinib treatment arm reported improvements, with statistical significance between treatment arms at week 12 and/or week 24 (respectively, P = 0.016 and 0.030; P = 0.035 and 0.128; and P = 0.047 and 0.031). The mean treatment effect according to change in ADAS-Cog score relative to baseline at weeks 12 and 24 was 6.8 and 7.6, respectively. Adverse events occurred more frequently with masitinib treatment (65% vs. 38% of patients); however, the majority of events were of mild or moderate intensity and transitory. Severe adverse events occurred at a similar frequency in the masitinib and placebo arms (15% vs. 13% of patients, respectively). Masitinib-associated events included gastrointestinal disorders, oedema, and rash. Conclusions: Masitinib administered as add-on therapy to standard care during 24 weeks was associated with slower cognitive decline in Alzheimer's disease, with an acceptable tolerance profile. Masitinib may therefore represent an innovative avenue of treatment in Alzheimer's disease. This trial provides evidence that may support a larger placebo-controlled investigation. 2011 Piette et al.; licensee BioMed Central Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/737/CN-00894737/frame.html>

Record #154 of 370



ID: CN-00888535

AU: Domenico M

AU: Polverino M

AU: Rosa C

AU: Ricci V

AU: Bisogno A

AU: Capasso A

TI: Xolair: A new monoclonal drug anti-IgE antibody for the treatment of allergic asthma.

SO: Biomedical research (Tokyo, Japan)

YR: 2011

VL: 22

NO: 1

PG: 111-9

XR: EMBASE 2011008411

PT: Journal: Article

KY: adult // *allergic asthma/dt [Drug Therapy] // article // body weight // clinical article // disease control // disease severity // dose calculation // drug efficacy // drug megadose // drug response // female // Global Evaluation of Treatment Effectiveness scale // human // immunoglobulin blood level // lung function // male // patient selection // quality of life // randomized controlled trial // rating scale // symptom // treatment duration // beta 2 adrenergic receptor stimulating agent/do [Drug Dose] // beta 2 adrenergic receptor stimulating agent/dt [Drug Therapy] // budesonide/dt [Drug Therapy] // budesonide/ih [Inhalational Drug Administration] // budesonide plus formoterol/dt [Drug Therapy] // budesonide plus formoterol/ih [Inhalational Drug Administration] // corticosteroid/do [Drug Dose] // corticosteroid/dt [Drug Therapy] // corticosteroid/ih [Inhalational Drug Administration] // corticosteroid/po [Oral Drug Administration] // formoterol/dt [Drug Therapy] // immunoglobulin E/ec [Endogenous Compound] // *omalizumab/ct [Clinical Trial] // *omalizumab/dt [Drug Therapy] // placebo // salbutamol/dt [Drug Therapy] // salmeterol/dt [Drug Therapy] // salmeterol/ih [Inhalational Drug Administration]

AB: Xolair is a monoclonal antibody that binds the C3 domain of IgEs, inducing a conformational change of the immunoglobulin, a concealment of FcRI and FcRII receptors binding sites, thus precluding binding by IgEs and therefore stopping the release of inflammation mediators. Xolair is indicated as add-on therapy to improve/control asthma in adult and adolescent patients (12 years of age and above) suffering from severe persistent allergic asthma. The aim of our work was to evaluate the Xolair efficacy in the asthma treatment. Six patients (4 men and 2 women aged 30 to 60 years) were selected for the treatment with Xolair. Previously, they were treated with high doses of long-acting beta2-agonists and inhaled corticosteroids, but they were not able to control their illness despite the assumption of such drugs. Xolair was administered for 32 weeks in addition to the traditional asthma therapy. Xolair dosage was calculated according to their weight and their IgE levels (IU/ml). The therapeutic response was evaluated according to the GETE (Global Evaluation of Treatment Effectiveness) scale. The

persistence of the response was defined, instead, by the number of patients continuing to respond positively to the treatment between the 16th and the 32nd week. 4 of 6 patients concluded the study. Patient number 2, in fact, had a body weight higher than 150 kg, so it was impossible to establish the necessary drug dosage. Patient number 6, instead, still had too high IgE values at his fourth checkup. Patient number 1 was fit in the efficacy level 2 (Good) at the 16th week, while at the 32nd week, he was in the level 1 (Excellent). Patient number 3 was at an efficacy level 1 yet from the 16th week, and that level was confirmed at the 32nd. In patient number 4, as well in that number 1, an increase of treatment efficacy was proved with a passage from level 2 to level 1. Finally, for the patient number 5, the efficacy level was Good both at the 16th and at the 32nd week (level 2). The re-sults obtained were positive for all patients and not only the persistence of a therapeutic re-sponse was confirmed, but in some cases there was an improvement of efficacy. Therefore, we can conclude that Xolair, administrated as an additional therapy, strongly improved the severe persistent IgE-mediated asthma. The anti-IgE Xolair treatment reduces the asthma frequency, also, it improved the patient life quality, by inducing positive effects on symp-toms and pulmonary function.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/535/CN-00888535/frame.html>

Record #155 of 370



ID: CN-00889937

AU: Verheye S

AU: Ramcharitar S

AU: Grube E

AU: Schofer JJ

AU: Witzenbichler B

AU: Kovac J

AU: Hauptmann KE

AU: Agostoni P

AU: Wiemer M

AU: Lefevre T

AU: Spaargaren R

AU: Serruys PW

AU: Garcia-Garcia HM

AU: Geuns RJ

TI: Six-month clinical and angiographic results of the STENTYS self-apposing stent in bifurcation lesions.

SO: EuroIntervention

YR: 2011

VL: 7

NO: 5

PG: 580-7

XR: EMBASE 2011601388

PT: Journal: Article

KY: adult // angiocardiology // artery diameter // article // *bare metal stent // cardiovascular disease/co [Complication] // controlled clinical trial // controlled study // coronary artery bypass graft // *coronary artery disease/dt [Drug Therapy] // *coronary artery disease/su [Surgery] // disease classification // *drug eluting stent // Europe // female // follow up // heart death // heart infarction/co [Complication] // human // intravascular ultrasound // major clinical study // male // multicenter study // percutaneous transluminal angioplasty // prospective study // treatment outcome // *everolimus/ct [Clinical Trial] // *everolimus/dt [Drug Therapy] // *nitinol // *paclitaxel/ct [Clinical Trial] // *paclitaxel/dt [Drug Therapy] // polysulfone // povidone // *rapamycin/ct [Clinical Trial] // *rapamycin/dt [Drug Therapy] // *umirolimus/ct [Clinical Trial] // *umirolimus/dt [Drug Therapy] // *zotarolimus/ct [Clinical Trial] // *zotarolimus/dt [Drug Therapy]

DOI: 10.4244/EIJV7I5A94

AB: Aims: We report the clinical and angiographic results of the OPEN I study, a multicentre prospective single-arm study evaluating both the drug-eluting and bare metal STENTYS stents in the treatment of coronary bifurcation lesions. Methods and results: The STENTYS stent is a provisional, self-expanding, nitinol stent with small interconnections that can be disconnected by balloon angioplasty in between the stent struts to provide access to the side branch (SB) and full ostium coverage. In nine European centres, 60 stents (33 BMS, 27 DES) were implanted in 63 patients (procedural success of 95.2%). Angiographic QCA and IVUS were used to measure acute gain and late loss. The Medina classification showed 35 patients (58%) had disease affecting the SB (true bifurcations) and 19 patients (32%) had disease in all three arms. The average bifurcation angulation pre-stenting was 60degree +21degree . Post-stenting, disconnection was performed on 90% of the stents implanted. In 18 cases, disconnection was followed by SB stenting with all SB stents successfully implanted. Post-stenting, the bifurcation angle was 51degree . The primary clinical endpoint, cumulative MACE at six months, was low

for DES (3.7%) but higher for BMS (27.3%) with the latter driven exclusively by clinically-driven TLR rates (3.7% vs. 24.2%). No cardiac deaths were recorded at six months and one patient had a non-Q wave infarct. The secondary angiographic endpoint of late luminal loss (LLL) was measured for both DES (paclitaxel) and BMS stents in the proximal main branch (MB), MB, distal MB as well as the SB. The values for DES were 0.39 mm, 0.42 mm, 0.40 mm and 0.16 mm, respectively. The values for BMS were 0.86 mm, 0.87 mm, 0.85 mm and 0.54 mm, respectively. Observed results using matched IVUS analysis at six months revealed an increase in mean stent area (mm²) for DES from 7.52±1.86 at baseline to 12.32±2.90 at six month follow-up (p <0.001); and for BMS from 7.95±1.40 to 11.56±2.22 (p <0.001), with no decrease in minimum lumen area (MLA) for DES (5.10 to 4.91) and a minimal decrease for BMS (5.74 to 5.15). Conclusions: This first-in-man (FIM) study on the STENTYS stent showed excellent procedural success and a relatively low MACE with competitively low LLL in both MB and SB at six months for the DES version and LLL comparable to other BMS for the BMS version. The disconnectable struts offered excellent "cross over" to T- stenting when necessary and the increased gains in stent area over time. Europa Edition 2011. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/937/CN-00889937/frame.html>

Record #156 of 370



ID: CN-00770643

AU: Sattler F

AU: Bhasin S

AU: He J

AU: Chou CP

AU: Castaneda-Sceppa C

AU: Yarasheski K

AU: Binder E

AU: Schroeder ET

AU: Kawakubo M

AU: Zhang A

AU: Roubenoff R

AU: Azen S

TI: Testosterone threshold levels and lean tissue mass targets needed to enhance skeletal muscle strength and function: the HORMA trial.

SO: Journals of gerontology. Series A, Biological sciences and medical sciences

YR: 2011

VL: 66

NO: 1

PG: 122-9

PM: PUBMED 21059836

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, U.S. Gov't, Non-P.H.S.

KY: Body Composition; Double-Blind Method; Human Growth Hormone [pharmacology]; Insulin-Like Growth Factor I [analysis]; Muscle Strength; Muscle, Skeletal [physiology]; Testosterone [blood]; Thinness; Aged[checkword]; Aged, 80 and over[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

DOI: 10.1093/gerona/glq183

AB: BACKGROUND: In the HORMA (Hormonal Regulators of Muscle and Metabolism in Aging) Trial, supplemental testosterone and recombinant human growth hormone (rhGH) enhanced lean body mass, appendicular skeletal muscle mass, muscle performance, and physical function, but there was substantial interindividual variability in outcomes. METHODS: One hundred and twelve men aged 65-90 years received testosterone gel (5 g/d vs 10 g/d via Leydig cell clamp) and rhGH (0 vs 3 vs 5 ?g/kg/d) in a double-masked 2 × 3 factorial design for 16 weeks. Outcomes included lean tissue mass by dual energy x-ray absorptiometry, one-repetition maximum strength, Margaria stair power, and activity questionnaires. We used pathway analysis to determine the relationship between changes in hormone levels, muscle mass, strength, and function. RESULTS: Increases in total testosterone of 1046 ng/dL (95% confidence interval = 1040-1051) and 898 ng/dL (95% confidence interval = 892-904) were necessary to achieve median increases in lean body mass of 1.5 kg and appendicular skeletal muscle mass of 0.8 kg, respectively, which were required to significantly enhance one-repetition maximum strength (? 30%). Co-treatment with rhGH lowered the testosterone levels (quantified using liquid chromatography-tandem mass spectrometry) necessary to reach these lean mass thresholds. Changes in one-repetition maximum strength were associated with increases in stair climbing power ($r = .26$, $p = .01$). Pathway analysis supported the model that changes in testosterone and insulin-like growth factor 1 levels are related to changes in lean body mass needed to enhance muscle performance and physical function. Testosterone's effects on physical activity were mediated through a different pathway because testosterone directly affected Physical Activity Score of the Elderly. CONCLUSIONS: To enhance muscle strength and physical function, threshold improvements in lean body mass and appendicular skeletal muscle mass are necessary and these can be achieved by targeting changes in

testosterone levels. rhGH augments the effects of testosterone. To maximize functional improvements, the doses of anabolic hormones should be titrated to achieve target blood levels.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/643/CN-00770643/frame.html>

Record #157 of 370



ID: CN-00887960

AU: Hempenius L

AU: Leeuwen BL

AU: Asselt DZB

AU: Hoekstra HJ

AU: Wiggers T

AU: Slaets JPJ

AU: Bock GH

TI: Structured analyses of interventions to prevent delirium.

SO: International Journal of Geriatric Psychiatry

YR: 2011

VL: 26

NO: 5

PG: 441-450

XR: EMBASE 2011179238

KY: aged // article // cardiopulmonary bypass // Cochrane Library // colon cancer // continuous infusion // controlled study // cost effectiveness analysis // *delirium/dt [Drug Therapy] // Diagnostic and Statistical Manual of Mental Disorders // effect size // elective surgery // epidural anesthesia // femur // femur neck fracture // general anesthesia // general practice // geriatric ward // heart surgery // hip arthroplasty // hip fracture // hip surgery // hospital admission // human // incidence // information retrieval // injection // intervention study // knee arthroplasty // Medline // orthopedic surgery // patient education // postoperative analgesia // primary prevention // publication // randomized controlled trial // screening // spine surgery // staff training // stomach surgery // structured interview // validity // ward //

diazepam/dt [Drug Therapy] // donepezil/ct [Clinical Trial] // donepezil/dt [Drug Therapy] // flunitrazepam/dt [Drug Therapy] // gabapentin/ct [Clinical Trial] // gabapentin/dt [Drug Therapy] // haloperidol/ct [Clinical Trial] // haloperidol/dt [Drug Therapy] // halothane // pethidine // placebo // risperidone/ct [Clinical Trial] // risperidone/dt [Drug Therapy] // rivastigmine/ct [Clinical Trial] // rivastigmine/dt [Drug Therapy]

DOI: <http://dx.doi.org/10.1002/gps.2560>

AB: Background: Delirium is one of the most serious complications in hospitalized elderly, with incidences ranging from 3-56%. The objective of this meta-analysis was two-fold, first to investigate if interventions to prevent delirium are effective and second to explore which factors increase the effectiveness of these interventions. Methods: An electronic search was carried out on articles published between January 1979 and July 2009. Abstracts were reviewed, data were extracted and methodologic quality was assessed by two independent reviewers. Effect sizes of the interventions were expressed as ORs (odds ratios) and 95%CI (confidence intervals). A random effect model was used to provide pooled ORs. To explore which factors increase the effectiveness of the interventions, ORs were stratified for several factors. Results: Sixteen relevant studies were found. Overall the included studies showed a positive result of any intervention to prevent delirium (pooled OR: 0.64; 95%CI: 0.46-0.88). The largest effect was seen in studies on populations with an incidence of delirium above 30% in the control group (pooled OR: 0.34; 95%CI: 0.16-0.71 versus 0.76; 95%CI: 0.60-0.97). Conclusions: Interventions to prevent delirium are effective. Interventions seem to be more effective when the incidence of delirium in the population under study is above 30%. To maximize the options for a cost-effective strategy of delirium prevention it might be useful to offer an intervention to a selected population. Copyright 2010 John Wiley & Sons, Ltd.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/960/CN-00887960/frame.html>

Record #158 of 370



ID: CN-00894854

AU: Clement C

AU: Capriotti JA

AU: Kumar M

AU: Hobden JA

AU: Foster TP

AU: Bhattacharjee PS

AU: Thompson HW

AU: Mahmud R

AU: Liang B

AU: Hill JM

TI: Clinical and antiviral efficacy of an ophthalmic formulation of dexamethasone povidone-iodine in a rabbit model of adenoviral keratoconjunctivitis.

SO: Investigative ophthalmology & visual science

YR: 2011

VL: 52

NO: 1

PG: 339-44

XR: EMBASE 2011271329

PT: Journal: Article


KY: Adenovirus 5 // *adenovirus infection/dt [Drug Therapy] // *adenovirus keratoconjunctivitis/dt [Drug Therapy] // animal experiment // animal model // animal tissue // antiviral activity // article // blepharitis // controlled study // drug efficacy // drug formulation // epiphora // eye toxicity // histopathology // *keratoconjunctivitis/dt [Drug Therapy] // neovascularization (pathology) // nonhuman // priority journal // pus // rabbit // randomized controlled trial // sclera disease // symptom // virus load // virus plaque // virus shedding // virus titration // *antivirus agent/ct [Clinical Trial] // *antivirus agent/cm [Drug Comparison] // *antivirus agent/dt [Drug Therapy] // *antivirus agent/to [Drug Toxicity] // *antivirus agent/pd [Pharmacology] // *antivirus agent/tp [Topical Drug Administration] // balanced salt solution // cidofovir/ct [Clinical Trial] // cidofovir/cm [Drug Comparison] // cidofovir/dt [Drug Therapy] // cidofovir/to [Drug Toxicity] // cidofovir/pd [Pharmacology] // cidofovir/tp [Topical Drug Administration] // *dexamethasone plus povidone iodine/ct [Clinical Trial] // *dexamethasone plus povidone iodine/cm [Drug Comparison] // *dexamethasone plus povidone iodine/dt [Drug Therapy] // *dexamethasone plus povidone iodine/to [Drug Toxicity] // *dexamethasone plus povidone iodine/pd [Pharmacology] // *dexamethasone plus povidone iodine/tp [Topical Drug Administration] // dexamethasone plus tobramycin/ct [Clinical Trial] // dexamethasone plus tobramycin/cm [Drug Comparison] // dexamethasone plus tobramycin/dt [Drug Therapy] // dexamethasone plus tobramycin/to [Drug Toxicity] // dexamethasone plus tobramycin/pd [Pharmacology] // dexamethasone plus tobramycin/tp [Topical Drug Administration] // fst 100 // unclassified drug

DOI: 10.1167/iovs.10-5944

AB: PURPOSE. To determine the efficacy of a new formulation of topical dexamethasone 0.1%/povidone-iodine 0.4% (FST-100) in reducing clinical symptoms and infectious viral titers in a rabbit model of adenoviral keratoconjunctivitis. METHODS. Rabbit corneas were inoculated bilaterally with 2×10^6 plaque-forming-units (PFU) of adenovirus type

5 (Ad5) after corneal scarification. Animals were randomized 1:1:1:1 (five rabbits per group) to FST-100, 0.5% cidofovir, tobramycin/ dexamethasone (Tobradex; Alcon Laboratories, Fort Worth, TX) ophthalmic suspension, and balanced salt solution (BSS; Alcon Laboratories). Treatment began 12 hours after viral inoculation and continued for 7 consecutive days. The eyes were clinically scored daily for scleral inflammation (injection), ocular neovascularization, eyelid inflammation (redness), friability of vasculature, inflammatory discharge (pus), and epiphora (excessive tearing). Eye swabs were collected daily before treatment for the duration of the study. Virus was eluted from the swabs and PFU determined by titration on human A549 cells, according to standard procedures. RESULTS. The FST-100 treatment resulted in significantly lower clinical scores ($P < 0.05$) than did the other treatments. The 0.5% cidofovir exhibited the most ocular toxicity compared with FST-100, tobramycin/dexamethasone, and balanced salt solution treatments. FST-100 and 0.5% cidofovir significantly ($P < 0.05$) reduced viral titers compared with tobramycin/ dexamethasone or balanced salt solution. CONCLUSIONS. FST-100 was the most efficacious in minimizing the clinical symptoms of adenovirus infection in rabbit eyes. FST-100 and 0.5% cidofovir were both equally effective in reducing viral titers and decreasing the duration of viral shedding. By providing symptomatic relief in addition to reducing infectious virus titers, FST-100 should be a valuable addition to treatment of epidemic adenoviral keratoconjunctivitis. 2011 The Association for Research in Vision and Ophthalmology, Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/854/CN-00894854/frame.html>

Record #159 of 370 

ID: CN-00890144

AU: Charafeddine KM

AU: Youssef AM

AU: Mahfouz RAR

AU: Saredidine DS

AU: Daher RT

TI: Comparison of neutrophil volume distribution width to C-reactive protein and procalcitonin as a proposed new marker of acute infection.

SO: Scandinavian journal of infectious diseases

YR: 2011

VL: 43

NO: 10

PG: 777-84

XR: EMBASE 2011495923

PT: Journal: Article

KY: adult // aged // article // bacterium culture // blood cell count // controlled clinical trial // controlled study // diagnostic accuracy // diagnostic test accuracy study // diagnostic value // female // Gram negative infection/di [Diagnosis] // Gram positive infection/di [Diagnosis] // human // inflammation // intensive care unit // intermethod comparison // major clinical study // male // medical history // *neutrophil // *neutrophil distribution width // postoperative infection/di [Diagnosis] // receiver operating characteristic // sensitivity and specificity // *sepsis/di [Diagnosis] // *C reactive protein/ec [Endogenous Compound] // *procalcitonin/ec [Endogenous Compound]

DOI: 10.3109/00365548.2011.585179

AB: Background: The aim of this study was to assess the use of neutrophil distribution width (NDW) and to compare it to C-reactive protein (CRP) and procalcitonin (PCT), in the detection of early sepsis in the intensive care unit. Methods: Subjects (N = 166) were divided into 4 groups: healthy, acute inflammatory non-infectious (AINI), localized infection, and systemic infection, according to clinical history and cultures. NDW, CRP, and PCT were compared among the different groups using multivariate analysis of variance (MANOVA). Diagnostic efficacy was assessed using receiver operating characteristic curves and areas under the curves (AUC). Results: The lowest meanNDW was found in the healthy group (n = 41), followed by the AINI (n = 20), localized infection (n = 55), and systemic infection (n = 50) groups. AUCNDW was 0.877 for infected (localized + systemic) vs non-infected (healthy + AINI) groups, and 0.965 for systemic infection vs non-infected groups. A cut-off of 21.9 resulted in 90% sensitivity, 92% specificity, 90% positive predictive value, and 92% negative predictive value (AUCNDW = 0.965, 95% confidence interval 0.9350.995). According to MANOVA, only NDW was able to differentiate an acute inflammatory process from early infection in postoperative patients, but not healthy from AINI subjects. Conclusions: NDW had the highest diagnostic accuracy and is available with the complete blood count with differential (CBC). It may be a promising parameter to aid in the diagnosis of acute infection in adults, provided the possibility of haematological disorders is first ruled out. 2011 Informa Healthcare.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/144/CN-00890144/frame.html>

Record #160 of 370



ID: CN-00889852

AU: Benoy IH

AU: Vanden Broeck D

AU: Ruymbeke MJ

AU: Sahebali S

AU: Arbyn M

AU: Bogers JJ

AU: Temmerman M

AU: Depuydt CE

TI: Prior knowledge of HPV status improves detection of CIN2+ by cytology screening.

SO: American journal of obstetrics and gynecology

YR: 2011

VL: 205

NO: 6

PG: 569.e1-569.e7

XR: EMBASE 2011644100

PT: Journal: Article

KY: adult // article // *cancer diagnosis // cancer grading // colposcopy // controlled clinical trial // controlled study // *cytology // diagnostic accuracy // diagnostic test accuracy study // female // human // knowledge // major clinical study // *papillomavirus infection // priority journal // prospective study // sensitivity and specificity // serodiagnosis // *serology // single blind procedure // *uterine cervix carcinoma in situ/di [Diagnosis] // Wart virus

DOI: 10.1016/j.ajog.2011.06.101

AB: Objective: The objective of the study was to investigate whether knowledge of human papillomavirus (HPV) deoxyribonucleic acid test results increases sensitivity of guided cytology screening for the detection of cervical intraepithelial neoplasia (CIN)-2 or higher-grade cervical lesions. Study Design: This was a prospective colposcopy-controlled study of 2905 BD SurePath samples to identify cases with CIN2+ within a 24 month follow-up period. Sensitivity and specificity to detect CIN2+ was evaluated, comparing guided cytology screening with and without prior knowledge of HPV status. Results: Prior knowledge of HPV status resulted in significantly higher detection rate of CIN2+ compared with screening blinded to HPV status ($P = .005$) with limited loss of specificity ($P = .026$). Gain in sensitivity is higher in older women (43.8%, $P = .008$) vs in younger women (10.2%, $P = .317$), whereas loss of specificity is more pronounced in younger women ($P < .001$) vs older women ($P = .729$). Conclusion: Guided

cytological screening performed with prior knowledge of HPV status results in an improved detection of CIN2 or higher-grade lesions. 2011 Mosby, Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/852/CN-00889852/frame.html>

Record #161 of 370



ID: CN-00895131

AU: Lakkis NA

AU: Atfeh AMA

AU: EL-Zein YR

AU: Mahmassani DM

AU: Hamadeh GN

TI: The effect of two types of sms-texts on the uptake of screening mammogram: A randomized controlled trial.

SO: Preventive Medicine

YR: 2011

VL: 53

NO: 4-5

PG: 325-327

XR: EMBASE 2011625207

KY: adult // aged // article // comparative study // controlled study // electronic medical record // female // follow up // health care utilization // human // major clinical study // *mammography // *mobile phone // priority journal // prospective study // randomized controlled trial // *reminder system // screening test

DOI: <http://dx.doi.org/10.1016/j.ypmed.2011.08.013>

AB: Objective: To compare the effect of two different types of short text message service (SMS-text) reminders on the uptake of screening mammogram. Methods: A randomized controlled trial was conducted in 2010 among females aged between 40 and 75, benefiting from the Health Insurance Plan at the American University of Beirut, whose cell phone numbers were available in their electronic medical records, and who did not do a mammogram in the past 2. years. The sample (n= 385) was randomly divided into two subgroups. The first

subgroup (n1 = 192) received a general SMS-text inviting its members to do a mammogram while the second subgroup (n2 = 193) received an additional informative SMS-text informing them about the benefits of mammogram screening. Results: 30.7% (59) of subgroup 1 and 31.6% (61) of subgroup 2 underwent a mammogram screening test during the 6. months follow up interval post-intervention (Chi-square test, p-value ≥ 0.05). There was no difference between the response rates in the two subgroups. Conclusion: A brief invitation SMS-text message for screening mammogram was found to be as effective as a detailed informative one. 2011 Elsevier Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/131/CN-00895131/frame.html>

Record #162 of 370



ID: CN-00887641

AU: Ameli M

AU: Kemper F

AU: Sarfeld A-S

AU: Kessler J

AU: Fink GR

AU: Nowak DA

TI: Arbitrary visuo-motor mapping during object manipulation in mild cognitive impairment and Alzheimer's disease: A pilot study.

SO: Clinical neurology and neurosurgery

YR: 2011

VL: 113

NO: 6

PG: 453-8

XR: EMBASE 2011313661

PT: Journal: Article

KY: adult // aged // *Alzheimer disease/dt [Drug Therapy] // article // clinical article // color vision test // controlled study // female // grip strength // human // intermethod comparison // male // *mild cognitive impairment/dt [Drug Therapy] // motor control // neurologic

examination // *object manipulation // randomized controlled trial // *visuomotor coordination // *donepezil/dt [Drug Therapy] // *galantamine/dt [Drug Therapy] // *memantine/dt [Drug Therapy] // *rivastigmine/dt [Drug Therapy]

DOI: 10.1016/j.clineuro.2011.01.011

AB: Empirical evidence for an essential role of the hippocampal system in arbitrary visuo-motor mapping suggests that acquisition and retrieval of arbitrary visuo-motor mapping might be impaired in mild cognitive impairment (MCI) and Alzheimer's disease (AD). The present pilot study investigated whether MCI of amnesic type or AD impact upon the capacity to scale grip force in a predictive manner to the mass of an object to be lifted based on learned associations between arbitrary colour cues and mass. Patients with MCI (n = 8) and AD (n = 8) grasped and lifted two different masses (400 g and 600 g) in random order using a precision grip between index finger and thumb. In a "no cue" experiment, a non-informative neutral visual stimulus was presented prior to each lift, thereby disallowing any prediction about which of the two masses was going to be lifted in the next trial. In a "cue" experiment an arbitrary colour cue provided advance information about which of the two masses to be lifted. In the "no cue" condition patients scaled their grip force according to the mass of the preceding lift. In the "cue" experiment neither patients with amnesic MCI nor those with AD were able to adjust their grip force based on visuo-motor mappings with arbitrary colour cues. These preliminary data suggest that the hippocampal system plays an essential role for arbitrary visuo-motor mapping in the grip-lift task. 2011 Elsevier B.V. All rights reserved.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/641/CN-00887641/frame.html>

Record #163 of 370



ID: CN-00770096

AU: Farlow MR

AU: Salloway S

AU: Tariot PN

AU: Yardley J

AU: Moline ML

AU: Wang Q

AU: Brand-Schieber E

AU: Zou H

AU: Hsu T

AU: Satlin A

TI: Effectiveness and tolerability of high-dose (23 mg/d) versus standard-dose (10 mg/d) donepezil in moderate to severe Alzheimer's disease: A 24-week, randomized, double-blind study.

SO: Clinical therapeutics

YR: 2010

VL: 32

NO: 7

PG: 1234-51

PM: PUBMED 20678673

PT: Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, P.H.S.

KY: Alzheimer Disease [drug therapy] [physiopathology];Cholinesterase Inhibitors [administration & dosage] [adverse effects] [therapeutic use];Cognition [drug effects];Dose-Response Relationship, Drug;Double-Blind Method;Indans [administration & dosage] [adverse effects] [therapeutic use];Piperidines [administration & dosage] [adverse effects] [therapeutic use];Severity of Illness Index;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1016/j.clinthera.2010.06.019

AB: BACKGROUND: Currently approved Alzheimer's disease (AD) treatments have been reported to provide symptomatic benefit, without proven impact on clinical progression. We hypothesized that the loss of initial therapeutic benefit over time may be mitigated by higher doses of a cholinesterase inhibitor. OBJECTIVE: The aim of this study was to determine the effectiveness and tolerability of increasing donepezil from 10 to 23 mg/d in patients with moderate to severe AD. METHODS: This randomized, double-blind study was conducted at 219 sites in Asia, Europe, Australia, North America, South Africa, and South America from June 6, 2007, to March 27, 2009. Patients aged 45 to 90 years with probable AD, Mini-Mental State Examination score 0 to 20 (moderate to severe impairment), and who were receiving donepezil 10 mg once daily for > or =12 weeks before the start of the study were eligible. Patients (n = 1467) were randomly assigned to receive high-dose donepezil (23 mg once daily) or standard-dose donepezil (10 mg once daily) for 24 weeks. Coprimary effectiveness measures were changes in cognition and global functioning, as assessed using least squares mean changes from baseline (LSM [SE] A) scores (last observation carried forward) on the Severe Impairment Battery (SIB; cognition) and the Clinician's Interview-Based Impression of Change Plus Caregiver Input scale (CIBIC+; global function rating) overall change score (mean [SD]) at week 24. Treatment-emergent adverse events (TEAEs) were assessed using

spontaneous patient/caregiver reporting and open-ended questioning; clinical laboratory testing (hematology, biochemistry, and urinalysis panels analyzed by a central laboratory); 12-lead ECG; and physical and neurologic examinations, including vital sign measurements.

RESULTS: The effectiveness analyses included 1371 patients (mean age, 73.8 years; 62.8% female; 73.5% white; weight range, 34.0-138.7 kg). A total of 296 of 981 patients (30.2%) withdrew from the donepezil 23-mg/d group; 87 of 486 patients (17.9%) withdrew from the donepezil 10-mg/d group. At study end (week 24), the LSM (SE) Delta in SIB score was significantly greater with donepezil 23 mg/d than with donepezil 10 mg/d (+2.6 [0.58] vs +0.4 [0.66], respectively; difference, 2.2; $P < 0.001$). The between-treatment difference in CIBIC+ score was nonsignificant (4.23 [1.07] vs 4.29 [1.07]). In post hoc analysis, LSM Delta in SIB score and CIBIC+ treatment effect at end point were greater with donepezil 23 mg/d than 10 mg/d in patients with more advanced AD compared with less impaired patients (SIB, +1.6 [0.78] vs -1.5 [0.88], respectively [$P < 0.001$]; CIBIC+, 4.31 [1.09] vs 4.42 [1.10] [$P = 0.028$]). TEAEs were reported in 710 of 963 patients (73.7%) who received donepezil 23 mg/d and in 300 of 471 patients (63.7%) who received donepezil 10 mg/d. With donepezil 23 mg/d, mild, moderate, and severe TEAEs were reported in 297 (30.8%), 332 (34.5%), and 81 (8.4%) patients, respectively; with donepezil 10 mg/d, these proportions were 147 (31.2%), 119 (25.3%), and 34 (7.2%). The 3 most common severe AEs reported with the 23-mg/d dose were nausea (9 patients [0.9%] vs 1 [0.2%] with the 10-mg/d dose), dizziness (7 [0.7%] vs 1 [0.2%]), and vomiting (6 [0.6%] vs 0). The most commonly reported TEAEs considered probably related to treatment with the 23-mg/d dose were nausea (59 patients [6.1%] vs 9 [1.9%] with the 10-mg/d dose), vomiting (48 [5.0%] vs 4 [0.8%]), and diarrhea (31 [3.2%] vs 7 [1.5%]). Thirteen deaths were reported during the study or within 30 days of study discontinuation (23 mg/d, 8 patients [0.8%]; 10 mg/d, 5 patients [1.1%]); all were considered unrelated to the study medication.

CONCLUSIONS: In this study in patients with moderate to severe AD, donepezil 23 mg/d was associated with greater benefits in cognition compared with donepezil 10 mg/d. The between-treatment difference in global functioning was not significant in the overall population. Patients with more advanced AD appeared to benefit from donepezil 23 mg/d on the assessment of global functioning, but this observation requires additional studies for confirmation. ClinicalTrials.gov identifier: NCT00478205.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/096/CN-00770096/frame.html>

Record #164 of 370



ID: CN-00892449

AU: Ghorbani A

AU: Chitsaz A

AU: Shishegar M

AU: Akbari M

TI: Evaluation of the effect of donepezil on cerebral blood flow velocity in Alzheimer's disease.

SO: Neurosciences (Riyadh, Saudi Arabia)

YR: 2010

VL: 15

NO: 3

PG: 172-6


XR: EMBASE 2011051677

PT: Journal: Article

KY: adult // aged // *Alzheimer disease/dt [Drug Therapy] // article // *blood flow velocity // *brain blood flow // case control study // clinical article // controlled clinical trial // diastole // Doppler echography // drug efficacy // drug mechanism // female // human // Iran // male // Mini Mental State Examination // posterior cerebral artery // systole // treatment duration // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy] // *donepezil/po [Oral Drug Administration] // *donepezil/pd [Pharmacology]

AB: Objectives: To evaluate the effect of Donepezil on cerebral blood flow velocity using non-invasive transcranial Doppler (TCD) sonography. Methods: This clinical trial was carried out in the Department of Neurology, Alzahra Hospital, Isfahan University of Medical Sciences, Isfahan, Iran from March 2008 to July 2009, on Alzheimer's disease (AD) patients in 2 groups of case and control, each consisting of 11 patients. The case group who received Donepezil medication was examined by TCD before (baseline), after 4 weeks of oral treatment with 5mg per day Donepezil, and a further 4 weeks of 10mg per day Donepezil, orally. The control group comprised AD patients who did not receive any medications, and were examined by TCD only once. Peak systolic (PSV), end-diastolic (EDV), and mean flow (MFV) velocities of the posterior cerebral artery (PCA) and the middle cerebral artery (MCA) was assessed by TCD. Also, mini-mental state examination (MMSE) was carried out. Results: There were no significant differences between the case and control groups, in terms of age and gender. In the case group, the mean MMSE score reached 20.2±2.8 from a baseline value of 15.8±3.3 after 4 weeks of oral treatment with 5mg/d Donepezil, and reached 20.6±3.9 after 4 more weeks at 10mg/d Donepezil. In the MCA, the difference in PSV and MFV values after 4 weeks of treatment with 10mg/d Donepezil was statistically significant compared with the baseline values. In PCA, the values of MFV and EDV after 4 weeks of treatment with 10mg/d Donepezil were statistically significant in comparison with the baseline value. Conclusion: Donepezil (10mg/d) increased cerebral blood flow velocity and MMSE score in our AD patients, but more extensive trials are recommended.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/449/CN-00892449/frame.html>

Record #165 of 370 

ID: CN-00742023

AU: Grasing K

AU: Mathur D

AU: Newton TF

AU: DeSouza C

TI: Donepezil treatment and the subjective effects of intravenous cocaine in dependent individuals.

SO: Drug and alcohol dependence

YR: 2010

VL: 107

NO: 1

PG: 69-75

PM: PUBMED 19836169

PT: Journal Article; Randomized Controlled Trial; Research Support, U.S. Gov't, Non-P.H.S.

KY: Behavior, Addictive [drug therapy];Cholinesterase Inhibitors [therapeutic use];Cocaine [administration & dosage] [pharmacology];Cocaine-Related Disorders [drug therapy] [psychology];Dose-Response Relationship, Drug;Drug Interactions;Indans [adverse effects] [therapeutic use];Infusions, Intravenous;Piperidines [adverse effects] [therapeutic use];Reinforcement (Psychology);Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1016/j.drugalcdep.2009.09.010

AB: Acetylcholinesterase (AChE) inhibitors increase synaptic levels of acetylcholine (ACh) by inhibiting its breakdown. Donepezil is a reversible AChE inhibitor that is clinically available and relatively selective for inhibiting AChE but not other cholinesterases. Because AChE inhibitors have been shown to decrease the reinforcing effects of cocaine in animals, our hypothesis was that pretreatment with donepezil would attenuate the perceived value and other positive subjective effects of cocaine. We conducted a within-subject, double-blind, placebo-controlled, laboratory-based evaluation of the subjective effects produced by intravenous cocaine in human subjects receiving oral donepezil. Following three days of daily treatment with 5mg of donepezil or oral placebo, participants received intravenous placebo or cocaine

(0.18 and 0.36 mg/kg). After a three-day washout period, participants were crossed over to the opposite oral treatment, which was followed by identical intravenous infusions. Donepezil was well-tolerated with only two drug-related adverse events reported that were mild and self-limiting. Treatment with donepezil increased ratings of 'any' and 'good' drug effect produced by low-dose cocaine, without modifying the response to high-dose cocaine. When collapsed across intravenous dose, treatment with donepezil decreased dysphoric effects and somatic symptoms, but did not modify the value of cocaine injections as determined by the Multiple Choice Questionnaire (MCQ). In summary, pretreatment with donepezil potentiated some measures for nonspecific and positive effects of low-dose cocaine. Across all intravenous treatments, participants receiving donepezil reported fewer somatic-dysphoric effects. Neither of these actions support the value of donepezil as a treatment for cocaine dependence.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/023/CN-00742023/frame.html>

Record #166 of 370



ID: CN-00749090

AU: Doody RS

AU: Ferris S

AU: Salloway S

AU: Yijun Sun null

AU: Goldman R

AU: Yikang Xu null

AU: Gao J

AU: Murthy AK

TI: Safety and tolerability of donepezil in mild cognitive impairment: open-label extension study.

SO: American journal of Alzheimer's disease and other dementias

YR: 2010

VL: 25

NO: 2

PG: 155-9

PM: PUBMED 19949165

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Amnesia [drug therapy] [psychology];Cholinesterase Inhibitors [administration & dosage] [adverse effects];Cognition Disorders [drug therapy] [psychology];Diarrhea [chemically induced];Double-Blind Method;Follow-Up Studies;Indans [administration & dosage] [adverse effects];Nausea [chemically induced];Neuropsychological Tests;Piperidines [administration & dosage] [adverse effects];Psychiatric Status Rating Scales;Severity of Illness Index;Sleep Initiation and Maintenance Disorders [chemically induced];Spasm [chemically induced];Time Factors;Treatment Outcome;Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1177/1533317509352334

AB: Following a 48-week, double-blind, randomized, placebo-controlled trial of donepezil in 821 patients with amnesic mild cognitive impairment (aMCI), safety and tolerability of donepezil (10 mg) were further evaluated in a 28-week extension study. Of 499 participants who completed the double-blind phase, 145 enrolled in the open-label study. Adverse events (AEs) were recorded throughout. Overall, 57.4% of participants in the donepezil/donepezil group and 62.3% in the placebo/donepezil group experienced an AE, with the most frequent treatment-emergent AEs being diarrhea, muscle spasms, insomnia, and nausea. Most were mild to moderate in severity and were more common in the first several weeks after treatment initiation. More participants in the placebo/donepezil group (22.1%) discontinued donepezil due to an AE compared with the donepezil/donepezil group (10.3%). These findings support the safety of donepezil in patients with aMCI. When compared with other studies, however, the data suggest that patients with Alzheimer's tolerate donepezil better than patients with MCI.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/090/CN-00749090/frame.html>

Record #167 of 370



ID: CN-00734882

AU: Feldman HH

AU: Doody RS

AU: Kivipelto M

AU: Sparks DL

AU: Waters DD

AU: Jones RW

AU: Schwam E

AU: Schindler R

AU: Hey-Hadavi J

AU: DeMicco DA

AU: Breazna A

TI: Randomized controlled trial of atorvastatin in mild to moderate Alzheimer disease: LEADe.

SO: Neurology

YR: 2010

VL: 74

NO: 12

PG: 956-64

PM: PUBMED 20200346

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [metabolism];Cholesterol, LDL [metabolism];Cholinergic Antagonists [therapeutic use];Double-Blind Method;Heptanoic Acids [therapeutic use];Hippocampus [pathology];Hydroxymethylglutaryl-CoA Reductase Inhibitors [therapeutic use];Magnetic Resonance Imaging;Organ Size [drug effects];Pyrroles [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1212/WNL.0b013e3181d6476a

AB: BACKGROUND: There is some evidence that statins may have a protective and symptomatic benefit in Alzheimer disease (AD). The LEADe study is a randomized controlled trial (RCT) evaluating the efficacy and safety of atorvastatin in patients with mild to moderate AD. METHODS: This was an international, multicenter, double-blind, randomized, parallel-group study. Subjects had mild to moderate probable AD (Mini-Mental State Examination score 13-25), were aged 50-90 years, and were taking donepezil 10 mg daily for > or 3 months prior to screening. Entry low-density lipoprotein cholesterol levels (LDL-C) were > 95 and < 195 mg/dL. Patients were randomized to atorvastatin 80 mg/day or placebo for 72 weeks followed by a double-blind, 8-week atorvastatin withdrawal phase. Coprimary endpoints were changes in cognition (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog]) and global

function (Alzheimer's Disease Cooperative Study Clinical Global Impression of Change [ADCS-CGIC]) at 72 weeks. RESULTS: A total of 640 patients were randomized in the study. There were no significant differences in the coprimary endpoints of ADAS-cog or ADCS-CGIC or the secondary endpoints. Atorvastatin was generally well-tolerated. CONCLUSIONS: In this large-scale randomized controlled trial evaluating statin therapy as a treatment for mild to moderate Alzheimer disease, atorvastatin was not associated with significant clinical benefit over 72 weeks. This treatment was generally well-tolerated without unexpected adverse events. Classification of evidence: This study provides Class II evidence that intensive lipid lowering with atorvastatin 80 mg/day in patients with mild to moderate probable Alzheimer disease (aged 50-90), taking donepezil, with low-density lipoprotein cholesterol levels between 95 and 195 mg/dL over 72 weeks does not benefit cognition (as measured by Alzheimer's Disease Assessment Scale-Cognitive Subscale) ($p = 0.26$) or global function (as measured by Alzheimer's Disease Cooperative Study Clinical Global Impression of Change) ($p = 0.73$) compared with placebo.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/882/CN-00734882/frame.html>

Record #168 of 370



ID: CN-00768274

AU: Wilkinson D

AU: Róman G

AU: Salloway S

AU: Hecker J

AU: Boundy K

AU: Kumar D

AU: Posner H

AU: Schindler R

TI: The long-term efficacy and tolerability of donepezil in patients with vascular dementia.

SO: International journal of geriatric psychiatry

YR: 2010

VL: 25

NO: 3

PG: 305-13

PM: PUBMED 19623601

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [psychology];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Cognition [drug effects];Dementia, Vascular [diagnosis] [drug therapy];Double-Blind Method;Indans [adverse effects] [therapeutic use];Neuropsychological Tests;Piperidines [adverse effects] [therapeutic use];Psychiatric Status Rating Scales;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1002/gps.2340

AB: OBJECTIVE: To determine the long-term tolerability and efficacy of donepezil in patients with vascular dementia (VaD). METHODS: International, multicentre, open-label, 30-week extension study of two 24-week, randomised, double-blind, placebo-controlled studies. Participants were ambulatory adults (59% female; mean age, 74.7 +/- 0.3) with a diagnosis of possible or probable VaD and without a diagnosis of Alzheimer's disease, who were medically stable and had completed one of two double-blind studies. All patients received donepezil 5 mg/day for the first 6 weeks, then 10 mg/day (clinician approval required). Assessments were performed at week 6 and every 12 weeks thereafter. The main outcome measure was the Alzheimer's disease Assessment Scale-cognitive subscale (ADAS-cog). Safety/tolerability measures included adverse events (AEs) and physical and laboratory evaluations. RESULTS: Of 1219 eligible patients, 885 (72.6%) were enrolled, of which 707 (79.9%) completed the study; 127 (14.4%) patients discontinued due to AEs. A mean reduction (0.6-1.15 points) from double-blind study baseline score to week 54 (end of open-label study) on the ADAS-cog was observed for patients who received donepezil continuously for 54 weeks. ADAS-cog scores remained stable in the group that initiated donepezil treatment during the extension study. Most common donepezil-related AEs were nausea (occurring in 5.3%) and diarrhoea (8.8%); no unexpected AEs attributable to donepezil occurred. CONCLUSION: These data suggest that donepezil improves cognition for up to 54 weeks in patients with VaD. Patients initiating donepezil in this extension study did not perform as well on the primary outcome measure as those initiating donepezil in the double-blind study.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/274/CN-00768274/frame.html>

Record #169 of 370



ID: CN-00751432

AU: Román GC

AU: Salloway S

AU: Black SE

AU: Royall DR

AU: Decarli C

AU: Weiner MW

AU: Moline M

AU: Kumar D

AU: Schindler R

AU: Posner H

TI: Randomized, placebo-controlled, clinical trial of donepezil in vascular dementia: differential effects by hippocampal size.

SO: Stroke; a journal of cerebral circulation

YR: 2010

VL: 41

NO: 6

PG: 1213-21

PM: PUBMED 20395618

PT: Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cognition [drug effects];Dementia, Vascular [drug therapy] [mortality] [physiopathology] [radiography];Double-Blind Method;Hippocampus [radiography];Indans [administration & dosage] [adverse effects];Nootropic Agents [administration & dosage] [adverse effects];Organ Size;Piperidines [administration & dosage] [adverse effects];Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1161/STROKEAHA.109.570077

AB: BACKGROUND AND PURPOSE: We sought to assess the efficacy and safety of donepezil in patients with vascular dementia (VaD) fulfilling National Institute of Neurological Disorders and Stroke-Association Internationale pour la Recherche et l'Enseignement en Neurosciences criteria. METHODS: This international, multicenter, 24-week trial was conducted from March 2003 to August 2005. Patients (N=974; mean age, 73.0 years) with probable or possible VaD were randomized 2:1 to receive donepezil 5 mg/d or placebo. Coprimary outcome measures

were scores on the Vascular-Alzheimer Disease Assessment Scale-Cognitive Subscale and Clinician's Interview-Based Impression of Change, plus carer interview. Analyses were performed for the intent-to-treat population with the last-observation-carried-forward method. RESULTS: Compared with placebo, donepezil-treated patients showed significant improvement from baseline to end point on the Vascular-Alzheimer Disease Assessment Scale-Cognitive Subscale (least-squares mean difference, -1.156; 95% CI, -1.98 to -0.33; $P < 0.01$) but not on the Clinician's Interview-Based Impression of Change, plus carer interview. Patients with hippocampal atrophy who were treated with donepezil demonstrated stable cognition versus a decline in the placebo-treated group; in those without atrophy, cognition improved with donepezil versus relative stability with placebo. Results on secondary efficacy measures were inconsistent. The incidence of adverse events was similar across groups. Eleven deaths occurred in the donepezil group (1.7%), similar to rates previously reported for donepezil trials in VaD, whereas no deaths occurred in the placebo group. CONCLUSIONS: Patients treated with donepezil 5 mg/d demonstrated significant improvement in cognitive, but not global, function. Donepezil was relatively well tolerated; adverse events were consistent with current labeling. Mortality in the placebo group was unexpectedly low. The differential treatment response of VaD patients by hippocampal size suggests that hippocampal imaging warrants further investigation for understanding VaD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/432/CN-00751432/frame.html>

Record #170 of 370



ID: CN-00768506

AU: Cummings J

AU: Jones R

AU: Wilkinson D

AU: Lopez O

AU: Gauthier S

AU: Waldemar G

AU: Zhang R

AU: Xu Y

AU: Sun Y

AU: Richardson S

AU: Mackell J

TI: Effect of donepezil on cognition in severe Alzheimer's disease: a pooled data analysis.

SO: Journal of Alzheimer's disease

YR: 2010

VL: 21

NO: 3

PG: 843-51

PM: PUBMED 20634594

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Cognition [drug effects];Cognition Disorders [drug therapy];Double-Blind Method;Indans [therapeutic use];Neuropsychological Tests;Piperidines [therapeutic use];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.3233/JAD-2010-100078

AB: To better characterize response to donepezil in patients with severe AD, Severe Impairment Battery (SIB) data were pooled from four donepezil clinical trials (N=904). Changes in SIB total and domain scores from baseline to week 24 were compared between placebo and donepezil treatment groups (observed case analysis). Analyses were stratified by baseline severity (Mini-Mental State Examination [MMSE] scores 1-5, 6-9, 10-12 and 13-17) to allow investigation of responses at different stages of cognitive impairment. Relationships to global and functional measures were explored. The difference between donepezil- and placebo-treated patients in least squares (LS) mean change in SIB total scores from baseline to week 24 was 6.22 ($p < 0.0001$, Cohen's d , 0.53). Treatment-placebo differences were statistically significant for each baseline severity stratum, being greatest for the MMSE 6-9 stratum (LS mean difference, 7.60; $p < 0.0001$, Cohen's d , 0.66). Treatment-placebo differences in LS mean change in SIB domain scores significantly favored donepezil for seven of nine domains (range, $p = 0.0056$ to $p < 0.0001$; Cohen's d , 0.17-0.48). Change in total SIB score correlated significantly with change in measures of activities of daily living and global status. These results indicate that donepezil provides cognitive benefits in patients with severe AD, including those most markedly impaired. The treatment effect size and correlation between improvements in SIB scores and functional and global outcome measures suggest the drug-placebo differences are clinically meaningful.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/506/CN-00768506/frame.html>

Record #171 of 370



ID: CN-00752532

AU: Modrego PJ

AU: Fayed N

AU: Errea JM

AU: Rios C

AU: Pina MA

AU: Sarasa M

TI: Memantine versus donepezil in mild to moderate Alzheimer's disease: a randomized trial with magnetic resonance spectroscopy.

SO: European journal of neurology

YR: 2010

VL: 17

NO: 3

PG: 405-12

PM: PUBMED 19874395

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [metabolism];Aspartic Acid [analogs & derivatives] [metabolism];Brain [drug effects] [metabolism];Cholinesterase Inhibitors [therapeutic use];Indans [therapeutic use];Magnetic Resonance Spectroscopy [methods];Memantine [therapeutic use];Neuropsychological Tests;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Protons;Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1111/j.1468-1331.2009.02816.x

AB: BACKGROUND AND PURPOSE: To compare memantine with the most prescribed cholinesterase inhibitor (donepezil) from a clinical viewpoint when administered in early phases of Alzheimer disease (AD), and to find out whether memantine may produce changes in brain metabolite concentrations in comparison with donepezil. METHODS: In this comparative rater-blinded parallel group randomized trial we recruited a consecutive sample of patients

with probable mild to moderate AD. At baseline we carried out neuropsychological assessment with mini-mental, Clinical Dementia Rating Scale (CDR), Blessed Dementia Rating Scale, Alzheimer's Disease Assessment Scale, cognitive part (ADAS-cog), neuropsychiatric inventory (NPI), and disability assessment for dementia (DAD), as well as (1)H magnetic resonance spectroscopy (MRS) in several areas of the brain. Patients were randomized to receive either donepezil or memantine for 6 months. After this elapse of time we repeated the same procedures and observed the changes in clinical scales (ADAS-cog, NPI, DAD), as well as the changes in metabolite levels in every area of exploration (temporal, pre-frontal, posterior cingulated (PCG), and occipital), especially those of N-acetyl-aspartate (NAA) which is regarded as a surrogate marker of neuronal density. RESULTS: A total of sixty-three patients completed the trial. We did not see significant differences in clinical scales and metabolite levels between those on donepezil (n = 32) and those on memantine (n = 31). In general, more patients worsened than improved on either of the drugs. The changes in the NAA/creatine ratio in the PCG correlated significantly with the changes in the ADAS-cog (P = 0.004). CONCLUSIONS: Donepezil and memantine have similar modest clinical and spectroscopic effect on mild to moderate AD. MRS could be useful to monitor progression of the disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/532/CN-00752532/frame.html>

Record #172 of 370



ID: CN-00779621

AU: Kishnani PS

AU: Heller JH

AU: Spiridigliozzi GA

AU: Lott I

AU: Escobar L

AU: Richardson S

AU: Zhang R

AU: McRae T

TI: Donepezil for treatment of cognitive dysfunction in children with Down syndrome aged 10-17.

SO: American journal of medical genetics. Part A

YR: 2010

VL: 152A

NO: 12

PG: 3028-35

PM: PUBMED 21108390

PT: Clinical Trial, Phase II; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adolescent; Behavior [drug effects]; Caregivers [psychology]; Cholinesterase Inhibitors [adverse effects] [pharmacology] [therapeutic use]; Cognition Disorders [drug therapy] [physiopathology]; Diarrhea [chemically induced]; Dose-Response Relationship, Drug; Double-Blind Method; Down Syndrome [drug therapy] [physiopathology]; Drug Tolerance; Indans [adverse effects] [pharmacology] [therapeutic use]; Learning [drug effects]; Neuropsychological Tests; Piperidines [adverse effects] [pharmacology] [therapeutic use]; Severity of Illness Index; Vomiting [chemically induced]; Child[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

DOI: 10.1002/ajmg.a.33730

AB: The objective of this 10-week, randomized, double-blind, placebo-controlled multicenter study was to assess the efficacy and safety of donepezil for the treatment of cognitive dysfunction exhibited by children with Down syndrome (DS). Intervention comprised donepezil (2.5-10 mg/day) in children (aged 10-17 years) with DS of mild-to-moderate severity. The primary measures were the Vineland-II Adaptive Behavior Scales (VABS-II) Parent/Caregiver Rating Form (PCRF) the sum of nine subdomain standardized scores and standard safety measures. Secondary measures included the VABS-II/PCRF scores on the following domains and their respective individual subdomains: Communication (receptive, expressive, and written); Daily Living Skills (personal, domestic, and community); Socialization (interpersonal relationships, play and leisure time, and coping skills), and scores on the Test of Verbal Expression and Reasoning, a subject-performance-based measure of expressive language. At baseline, 129 participants were assigned treatment with donepezil or placebo. During the double-blind phase, VABS II/PCRF sum of the nine subdomain standardized scores, called v-scores, improved significantly from baseline in both groups ($P < 0.0001$), with no significant between-group differences. This trial failed to demonstrate any benefit for donepezil versus placebo in children and adolescents with DS, although donepezil appeared to be well tolerated.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/621/CN-00779621/frame.html>

Record #173 of 370



ID: CN-00753455

AU: Almeida S

AU: Filipe A

AU: Neves R

AU: Desjardins I

AU: Shink E

AU: Castillo A

TI: Bioequivalence study of two different tablet formulations of donepezil using truncated areas under the curve. A single-center, single-dose, randomized, open-label, 2-way crossover study under fasting conditions.

SO: Arzneimittel-Forschung

YR: 2010

VL: 60

NO: 3

PG: 116-23

PM: PUBMED 20422942

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Analysis of Variance;Area Under Curve;Calibration;Chemistry, Pharmaceutical;Cross-Over Studies;Data Interpretation, Statistical;Electrocardiography [drug effects];Fasting [metabolism];Indans [administration & dosage] [adverse effects] [pharmacokinetics];Mass Spectrometry;Nootropic Agents [administration & dosage] [adverse effects] [pharmacokinetics];Piperidines [administration & dosage] [adverse effects] [pharmacokinetics];Tablets;Tandem Mass Spectrometry;Therapeutic Equivalency;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

DOI: 10.1055/s-0031-1296259

AB: BACKGROUND: Donepezil hydrochloride (CAS 120014-06-4) is a piperidine-based, reversible inhibitor of the enzyme acetylcholinesterase (AChE). It is postulated to exert its therapeutic effect by enhancing cholinergic function. This is accomplished by increasing the concentration of acetylcholine (ACh) through reversible inhibition of its hydrolysis by AChE. OBJECTIVE: The aim of this study was to assess the bioequivalence of a new donepezil 10 mg formulation (test formulation) vs. the reference product, as required by European regulatory authorities for the marketing of a generic product. Additionally, the applicability of the

truncated area under the plasma concentration curve (AUC) approach to this drug and under these test conditions was determined. METHODS: This was a single center, randomized, single-dose, open-label, 2-way crossover study in healthy volunteers under fasting conditions. Plasma samples were collected up to 288 h post-dosing and (+)-donepezil and (-)-donepezil plasma levels were determined by reverse liquid chromatography and by tandem mass spectrometry detection (ie, the LCMS/MS method). Pharmacokinetic parameters were calculated using non-compartmental analysis. Area under the concentration-time curve from time zero to the time of the last non-zero concentration (AUC(last)) and maximum observed concentration (C(max)) were the main evaluation criteria, while area under the concentration-time curve from time zero to infinity (AUC(inf)) was also analyzed for additional information. For the assessment of the applicability of the truncated AUC approach, AUCs truncated at 24, 48, 72, 96, 144, 192, 240, and 288 h were calculated. All of the abovementioned pharmacokinetic parameters were analyzed using 90% geometric confidence interval of the ratio (T/R) of least-squares means from the ANOVA of the ln-transformed parameter. Tolerability was monitored using physical examination, including vital sign measurements and laboratory analysis. RESULTS: According to the classical approach, the 90% geometric confidence intervals obtained by analysis of variance for AUC(last), C(max) and AUC(inf) were within the predefined ranges (80.00-125.00%) for both analytes. Truncated AUCs were also in all cases within the predefined ranges for acceptance of bioequivalence. CONCLUSION: Bioequivalence between test and reference formulations, both in terms of rate and extension of absorption, under fasting conditions, was concluded according to European guidelines. Both formulations were well tolerated. The conclusion of bioequivalence was also supported using the truncated AUCs approach.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/455/CN-00753455/frame.html>

Record #174 of 370



ID: CN-00750624

AU: Cornelli U

TI: Treatment of Alzheimer's disease with a cholinesterase inhibitor combined with antioxidants.

SO: Neuro-degenerative diseases

YR: 2010

VL: 7

NO: 1-3

PG: 193-202

PM: PUBMED 20224285

PT: Clinical Trial; Journal Article; Randomized Controlled Trial

KY: Alzheimer Disease [drug therapy];Antioxidants [therapeutic use];Bisphenol A-Glycidyl Methacrylate [therapeutic use];Cholinesterase Inhibitors [therapeutic use];Cohort Studies;Double-Blind Method;Drug Therapy, Combination [methods];Homocysteine [blood];Indans [therapeutic use];Models, Biological;Oxidative Stress [drug effects];Piperidines [therapeutic use];Polyurethanes [therapeutic use];Proteoglycans [blood];Reactive Oxygen Species [blood];Time Factors;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-COMP MED: SR-DEMENTIA

DOI: 10.1159/000295663

AB: A formula (formula F) was prepared to counteract oxidative stress (OS) in the brain. The formula contained the most common antioxidants and was intended to: (a) protect proteins, lipids, DNA and proteoglycans from oxidation (carnosine, coenzyme Q(10), vitamin E, vitamin C, beta-carotene, selenium, L-cysteine and ginkgo biloba); (b) reduce homocysteine (HCy) blood levels (vitamins B(6), B(9) and B(12)), and (c) sustain the pentose phosphate cycle in circulating cells (vitamins B(1), B(2) and B(3)). Formula F contained low doses of each antioxidant component and was administered in a two-phase ampoule. A cohort of 52 patients (21 males and 31 females) affected with moderate probable AD (according to NINCDS-ARDA and NINCDS-AIREN criteria) already being treated with donepezil (5 mg/day for at least two months) was randomly divided into two groups, and followed for 6 months. A double-blind design was used in which 26 cases were treated once a day with formula F plus donepezil, and the other 26 with placebo plus donepezil. The level of OS was measured on the basis of a d-ROMs test (which measures plasma hydroperoxides), plasma HCy and glutathione, and percentage of sickle erythrocytes. The two patient groups were comparable for all variables (age, sex, concomitant diseases, ApoE epsilon4, MMSE II score, OS, antioxidant reserve and sickle erythrocytes). Forty-eight subjects completed the trial. Significant decreases in OS and HCy were only observed when there was an increase in glutathione (in erythrocytes) and a decrease in sickle erythrocytes in patients treated with formula F. The MMSE II score remained almost the same in the group treated with donepezil and placebo, whereas some significant improvements were found in the group treated with donepezil plus formula F.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/624/CN-00750624/frame.html>

Record #175 of 370



ID: CN-00760149

AU: Chung KA

AU: Lobb BM

AU: Nutt JG

AU: Horak FB

TI: Effects of a central cholinesterase inhibitor on reducing falls in Parkinson disease.

SO: Neurology

YR: 2010

VL: 75

NO: 14

PG: 1263-9

PM: PUBMED 20810998

PT: Clinical Trial; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, Non-P.H.S.

KY: Cholinesterase Inhibitors [pharmacology] [therapeutic use];Cross-Over Studies;Disability Evaluation;Double-Blind Method;Indans [pharmacology] [therapeutic use];Parkinson Disease [complications] [drug therapy];Piperidines [pharmacology] [therapeutic use];Postural Balance [drug effects];Sensation Disorders [drug therapy] [etiology];Severity of Illness Index;Statistics, Nonparametric;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1212/WNL.0b013e3181f6128c

AB: OBJECTIVE: To investigate if a central cholinesterase inhibitor will reduce falling frequency in subjects with Parkinson disease (PD) with advanced postural instability. BACKGROUND: Falling due to postural instability is a significant problem in advancing PD, and is minimally impacted by dopaminergic therapy. Anticholinergic medications increase falling in the elderly. Further, CNS cholinergic neuron loss occurs in PD. We hypothesized that acetylcholine augmentation may reduce frequent falling in subjects with PD. METHODS: We enrolled 23 subjects with PD who reported falling or nearly falling more than 2 times per week. In a randomized, placebo-controlled, crossover design, subjects were given 6 weeks of donepezil or placebo with a 3-week washout between phases. The primary outcomes were daily falls and near falls reported on postcards. Secondary outcomes included scores on the Activities of Balance Confidence Scale, Berg Balance Scale, Clinical Global Impression of Change, Folstein Mini-Mental State Examination, and the motor section of the Unified Parkinson's Disease Rating Scale. RESULTS: Fall frequency per day on placebo was 0.25 ± 0.08 (SEM) compared with 0.13 ± 0.03 on donepezil ($p < 0.05$). The frequency of near falls was not significantly different between phases. The secondary outcomes did not differ; however, there was a trend to improvement on the subject-completed Global Impression of Change scale. CONCLUSIONS: Subjects with PD fell approximately half as often during the 6 weeks on donepezil than on placebo. Larger trials of cholinergic augmentation are warranted in subjects with PD with

frequent falls. Classification of evidence: This study provides Class II evidence that donepezil (maximum 10 mg per day) significantly reduced the number of falls in patients with PD (0.13 falls/day, SEM = 0.03) than when taking placebo (0.25 falls/day, SEM = 0.08, $p = 0.049$).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/149/CN-00760149/frame.html>

Record #176 of 370



ID: CN-00730707

AU: Akhondzadeh S

AU: Shafiee Sabet M

AU: Harirchian MH

AU: Togha M

AU: Cheraghmakani H

AU: Razeghi S

AU: Hejazi SS

AU: Yousefi MH

AU: Alimardani R

AU: Jamshidi A

AU: Rezazadeh SA

AU: Yousefi A

AU: Zare F

AU: Moradi A

AU: Vossoughi A

TI: A 22-week, multicenter, randomized, double-blind controlled trial of *Crocus sativus* in the treatment of mild-to-moderate Alzheimer's disease.

SO: Psychopharmacology

YR: 2010

VL: 207

NO: 4

PG: 637-43

PM: PUBMED 19838862

PT: Clinical Trial, Phase II; Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [physiopathology];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Crocus [chemistry];Double-Blind Method;Indans [adverse effects] [therapeutic use];Iran;Piperidines [adverse effects] [therapeutic use];Plant Extracts [adverse effects] [therapeutic use];Psychiatric Status Rating Scales;Severity of Illness Index;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-COMP MED: SR-DEMENTIA

DOI: 10.1007/s00213-009-1706-1

AB: RATIONALE: There is increasing evidence to suggest the possible efficacy of *Crocus sativus* (saffron) in the management of Alzheimer's disease (AD). OBJECTIVE: The purpose of the present investigation was to assess the efficacy of *C. sativus* in the treatment of patients with mild-to-moderate AD. METHODS: Fifty-four Persian-speaking adults 55 years of age or older who were living in the community were eligible to participate in a 22-week, double-blind study of parallel groups of patients with AD. The main efficacy measures were the change in the Alzheimer's Disease Assessment Scale-cognitive subscale and Clinical Dementia Rating Scale-Sums of Boxes scores compared with baseline. Adverse events (AEs) were systematically recorded. Participants were randomly assigned to receive a capsule saffron 30 mg/day (15 mg twice per day) or donepezil 10 mg/day (5 mg twice per day). RESULTS: Saffron at this dose was found to be effective similar to donepezil in the treatment of mild-to-moderate AD after 22 weeks. The frequency of AEs was similar between saffron extract and donepezil groups with the exception of vomiting, which occurred significantly more frequently in the donepezil group. CONCLUSION: This phase II study provides preliminary evidence of a possible therapeutic effect of saffron extract in the treatment of patients with mild-to-moderate Alzheimer's disease. This trial is registered with the Iranian Clinical Trials Registry (IRCT138711051556N1).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/707/CN-00730707/frame.html>

Record #177 of 370



ID: CN-00756209

AU: Doody RS

TI: "Donepezil treatment of patients with MCI: A 48-week randomized, placebo-controlled trial": Comment': reply from the authors

SO: Neurology

YR: 2010

VL: 73

NO: 18

PG: 1515

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/209/CN-00756209/frame.html>

Record #178 of 370



ID: CN-00761124

AU: Schwam E

AU: Xu Y

TI: Cognition and function in Alzheimer's disease: identifying the transitions from moderate to severe disease.

SO: Dementia and geriatric cognitive disorders

YR: 2010

VL: 29

NO: 4

PG: 309-16

PM: PUBMED 20395684


PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [drug therapy] [physiopathology] [psychology];Cognition;Disability Evaluation;Double-Blind Method;Indans [therapeutic use];Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Severity of Illness Index;Humans[checkword]

DOI: 10.1159/000269837

AB: BACKGROUND/AIMS: Cognitive and functional decline define the transition from moderate to severe Alzheimer's disease (AD); however, specific relationships between deteriorating cognition and functional abilities are less well characterized. Such relationships are important in care planning and understanding patient needs. Objectives of this post hoc analysis of data from a multicenter randomized double-blind placebo-controlled study were to describe changes in Severe Impairment Battery (SIB) scores over 6 months in patients with moderate to severe AD (MSAD), including an assessment of donepezil treatment on SIB scores, and to potentially identify a cognitive transition point associated with predicted functional disability. **METHODS:** The study comprised 290 patients with MSAD (standardized Mini-Mental State Examination score, 5-17) treated with donepezil 5-10 mg/day or matching placebo. Measurements were SIB, Functional Rating Scale, and Disability Assessment for Dementia. **RESULTS:** The largest decline in ability to perform basic activities of daily living (bADLs) occurred in placebo-treated patients with a baseline SIB score of approximately 70. Changes were reduced in the donepezil-treated group. **CONCLUSIONS:** This post hoc exploratory analysis suggests that a transition point between moderate and severe AD exists at a SIB score of approximately 70 and is associated with predictably declining bADLs.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/124/CN-00761124/frame.html>

Record #179 of 370 

ID: CN-00783439

AU: Poddar K

AU: Kant S

AU: Singh A

AU: Langade D

TI: Improvement in cognitive impairment with donepezil in post-stroke patients.

SO: International journal of stroke

YR: 2010

VL: 5

NO: Suppl 2

PG: 368

CC: SR-STROKE

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/439/CN-00783439/frame.html>

Record #180 of 370



ID: CN-00780365

AU: Matsuda O

AU: Shido E

AU: Hashikai A

AU: Shibuya H

AU: Kouno M

AU: Hara C

AU: Saito M

TI: Short-term effect of combined drug therapy and cognitive stimulation therapy on the cognitive function of Alzheimer's disease.

SO: Psychogeriatrics

YR: 2010

VL: 10

NO: 4

PG: 167-72

PM: PUBMED 21159050

PT: Comparative Study; Controlled Clinical Trial; Journal Article

KY: Alzheimer Disease [therapy];Cholinesterase Inhibitors [therapeutic use];Combined Modality Therapy;Follow-Up Studies;Indans [therapeutic use];Mathematics;Neuropsychological Tests;Piperidines [therapeutic use];Problem Solving;Reading;Verbal Learning;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1111/j.1479-8301.2010.00335.x

AB: BACKGROUND: Acetylcholinesterase inhibitors (i.e. donepezil) are known to benefit Alzheimer's disease (AD) patients. However, the combined effects of acetylcholinesterase and cognitive stimulation therapy (CST) are still debated. The present study examined their

combined effects on the progression of cognitive decline in AD. METHODS: The present study was a non-randomized controlled study and included two groups of patients with AD (i.e. CST group and control group). The CST group consisted of 31 patients with AD who received donepezil and weekly, 30-min CST sessions over the course of 7 weeks. The control group consisted of 18 patients who received only donepezil. Changes in cognitive abilities were assessed with Hasegawa's Dementia Scale-Revised (HDS-R) and were statistically analyzed by repeated-measure analysis of variance (anova). RESULTS: ANOVA showed a significant group \times time interaction effect on the HDS-R score. HDS-R scores for the CST group increased significantly during the intervention period, whereas the scores for the control group did not increase. Differences between the means of pre- and post-test HDS-R scores were significantly different between the groups; scores were significantly higher for the CST group than the control group. The groups differed significantly in the proportion of subjects whose score increased by more than four points on the HDS-R (Fisher's exact test, $P < 0.05$; 8 patients (25.8%) in the CST group and none (0.0%) in the control group). CONCLUSIONS: These results suggest that CST is one of the important non-pharmacological treatment strategies for patients with AD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/365/CN-00780365/frame.html>

Record #181 of 370



ID: CN-00752183

AU: Okahara K

AU: Ishida Y

AU: Hayashi Y

AU: Inoue T

AU: Tsuruta K

AU: Takeuchi K

AU: Yoshimuta H

AU: Kiue K

AU: Ninomiya Y

AU: Kawano J

AU: Yoshida K

AU: Noda S

AU: Tomita S

AU: Fujimoto M

AU: Hosomi J

AU: Mitsuyama Y

TI: Effects of Yokukansan on behavioral and psychological symptoms of dementia in regular treatment for Alzheimer's disease.

SO: Progress in neuro-psychopharmacology & biological psychiatry

YR: 2010

VL: 34

NO: 3

PG: 532-6

PM: PUBMED 20170698

PT: Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Behavioral Symptoms [drug therapy] [etiology];Dementia [complications] [drug therapy];Drugs, Chinese Herbal [therapeutic use];Neuropsychological Tests;Psychiatric Status Rating Scales;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-COMP MED: SR-DEMENTIA

DOI: 10.1016/j.pnpbp.2010.02.013

AB: Yokukansan (YKS) is used frequently against behavioral and psychological symptoms of dementia (BPSD) together with donepezil in patients with Alzheimer's disease (AD). Here, we investigated the efficacy and safety of YKS in patients with AD in a non-blinded, randomized, parallel-group comparison study. Patients who had at least one symptom score of four or more on the Neuropsychiatric Inventory (NPI) subscales were enrolled in the study. The subjects were randomly assigned to the YKS-treated group (YKS/donepezil combination therapy group) and the non-YKS-treated group (donepezil monotherapy group). TSUMURA Yokukansan (TJ-54, 7.5g, t.i.d.) was administered in a four-week study treatment period. The subjects were evaluated twice at the start (Week 0) and completion (Week 4) of the study treatment in terms of NPI, Mini-Mental Status Examination (MMSE), Disability Assessment for Dementia (DAD), Zarit Burden Interview, and Self-rating Depression Scale (SDS). The efficacy analysis was performed in 29 patients (YKS-treated group) and 32 patients (non-YKS-treated group). The NPI total score improved significantly more in the YKS-treated group than in the non-YKS-treated group. In the NPI subscales of agitation/aggression and irritability/lability, the YKS-treated group showed significantly greater improvement than the non-YKS-treated group, but

no statistically significant improvement was seen with YKS in the other subscales. There were no significant differences between the YKS-treated group and the non-YKS-treated group in MMSE, DAD, Zarit Burden Interview and SDS. No adverse reactions were noted in either group. The results of this study showed that YKS is safe and effective in the treatment of BPSD in AD patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/183/CN-00752183/frame.html>

Record #182 of 370



ID: CN-00768919

AU: Rokem A

AU: Landau AN

AU: Garg D

AU: Prinzmetal W

AU: Silver MA

TI: Cholinergic enhancement increases the effects of voluntary attention but does not affect involuntary attention.

SO: Neuropsychopharmacology

YR: 2010

VL: 35

NO: 13

PG: 2538-44

PM: PUBMED 20811340

PT: Controlled Clinical Trial; Journal Article; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Attention [drug effects] [physiology];Cholinesterase Inhibitors [pharmacology];Cues;Indans [pharmacology];Piperidines [pharmacology];Psychomotor Performance [drug effects] [physiology];Reaction Time [drug effects] [physiology];Spatial Behavior [drug effects] [physiology];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1038/npp.2010.118

AB: Voluntary visual spatial attention can be allocated in a goal-oriented manner to locations containing behaviorally relevant information. In contrast, involuntary attention is automatically captured by salient events. Allocation of attention is known to be modulated by release of the neurotransmitter acetylcholine (ACh) in cerebral cortex. We used an anti-predictive spatial cueing task to assess the effects of pharmacological enhancement of cholinergic transmission on behavioral measures of voluntary and involuntary attention in healthy human participants. Each trial began with the presentation of a cue in a peripheral location. In 80% of the trials, a target then appeared in a location opposite the cue. In the remaining 20% of trials, the target appeared in the cue location. For trials with short stimulus onset asynchrony (SOA) between cue and target, involuntary capture of attention resulted in shorter reaction times (RTs) to targets presented at the cue location. For long SOA trials, allocation of voluntary attention resulted in the opposite pattern: RTs were shorter when the target appeared in the expected (opposite) location. Each subject participated in two sessions: one in which the cholinesterase inhibitor donepezil was administered to increase synaptic ACh levels and one in which placebo was administered. Donepezil selectively improved performance (reduced RT) for long SOA trials in which targets appeared in the expected location. Thus, cholinergic enhancement augments the benefits of voluntary attention but does not affect involuntary attention, suggesting that they rely on different neurochemical mechanisms.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/919/CN-00768919/frame.html>

Record #183 of 370



ID: CN-00738456

AU: Anon


TI: [Public title] The effect of cognitive function as measured by repeated cognitive measures after 12 weeks treatment with donepezil; [Scientific title] A randomised, double-blind, placebo-controlled, parallel design, multicentre study in patients with mild to moderate Alzheimer's disease to investigate the effect on cognitive function as measured by repeated CogState testing in relation to effects on traditional cognitive measures after 12 weeks

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2010

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/456/CN-00738456/frame.html>

Record #184 of 370 

ID: CN-00738366

AU: Anon


TI: [Public title] A study to evaluate the safety, tolerability, and blood levels of PF-03654746 in subjects with mild to moderate Alzheimer's disease; [Official/Scientific title] A phase 1, double-blind, placebo-controlled, sponsor-open, randomized, multiple dose study to evaluate the safety, tolerability, and pharmacokinetics of PF-03654746 in mild to moderate Alzheimer's disease patients on stable donepezil therapy

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2010

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/366/CN-00738366/frame.html>

Record #185 of 370 

ID: CN-00738504

AU: Anon


TI: [Public title] A healthy volunteer study to evaluate reversibility of induced impairment of cognition; [Scientific title] A single-centre, randomised, double-blind, placebo-controlled, four-period cross-over study to evaluate the scopolamine cognition model in healthy male subjects using AZD1446 and donepezil versus placebo

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2010

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/504/CN-00738504/frame.html>

Record #186 of 370 

ID: CN-00769784

AU: Gold M

AU: Alderton C

AU: Zvartau-Hind M

AU: Egginton S

AU: Saunders AM

AU: Irizarry M

AU: Craft S

AU: Landreth G

AU: Linnamägi U

AU: Sawchak S

TI: Rosiglitazone monotherapy in mild-to-moderate Alzheimer's disease: results from a randomized, double-blind, placebo-controlled phase III study.

SO: Dementia and geriatric cognitive disorders

YR: 2010

VL: 30

NO: 2

PG: 131-46

PM: PUBMED 20733306


PT: Clinical Trial, Phase III; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alleles;Alzheimer Disease [drug therapy] [genetics] [metabolism] [physiopathology];Apolipoproteins E [genetics];Cholinesterase Inhibitors [administration & dosage] [adverse effects];Drug-Related Side Effects and Adverse Reactions;Edema [chemically induced];Genotype;Hypoglycemic Agents [administration & dosage] [adverse effects];Indans [administration & dosage] [adverse effects];Intelligence Tests;Interview, Psychological;Nasopharyngitis [chemically induced];PPAR gamma [agonists];Piperidines [administration & dosage] [adverse effects];Thiazolidinediones [administration & dosage] [adverse effects];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1159/000318845

AB: BACKGROUND/AIMS: A phase II study of the peroxisome proliferator-activated receptor- γ agonist rosiglitazone extended release (RSG XR) in mild-to-moderate Alzheimer's disease (AD) detected a treatment benefit to cognition in apolipoprotein E(APOE)- ϵ 4-negative subjects. The current phase III study with prospective stratification by APOE genotype was conducted to confirm the efficacy and safety of RSG XR in mild-to-moderate AD. An open-label extension study assessed the long-term safety and tolerability of 8 mg RSG XR. METHODS: This double-blind, randomized, placebo-controlled study enrolled 693 subjects. Within 2 APOE allelic strata (ϵ 4-positive, ϵ 4-negative), subjects were randomized (2:2:2:1) to once-daily placebo, 2 mg RSG XR, 8 mg RSG XR or 10 mg donepezil (control). Coprimary endpoints were change from baseline to week 24 in the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-Cog) score, and week 24 Clinician's Interview-Based Impression of Change plus caregiver input (CIBIC+). RESULTS: At week 24, no significant differences from placebo in change from baseline in coprimary endpoints were detected with either the RSG XR dose in APOE- ϵ 4-negative subjects or overall. For donepezil, no significant treatment difference was detected in ADAS-Cog; however, a significant difference was detected ($p = 0.009$) on the CIBIC+. Peripheral edema was the most common adverse event for 8 mg RSG XR (15%) and placebo (5%), and nasopharyngitis for 2 mg RSG XR (7%). CONCLUSION: No evidence of efficacy of 2 mg or 8 mg RSG XR monotherapy in cognition or global function was detected in the APOE- ϵ 4-negative or other analysis populations. The safety and tolerability of RSG XR was consistent with its known pharmacology.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/784/CN-00769784/frame.html>

Record #187 of 370 

ID: CN-00767437

AU: Brumberg HL

AU: Kowalski L

AU: Troxell-Dorgan A

AU: Gettner P

AU: Konstantino M

AU: Poulsen JF

AU: Ehrenkranz RA

TI: Randomized trial of enteral protein and energy supplementation in infants less than or equal to 1250 g at birth.

SO: Journal of perinatology

YR: 2010

VL: 30

NO: 8

PG: 517-21

PM: PUBMED 20200540

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Dietary Fats [administration & dosage];Dietary Proteins [administration & dosage];Enteral Nutrition;Infant Formula;Infant Nutritional Physiological Phenomena;Infant, Newborn;Infant, Very Low Birth Weight;Triglycerides [administration & dosage];Weight Gain;Female[checkword];Humans[checkword];Infant[checkword];Male[checkword]

CC: SR-COMP MED: SR-ENDOC: SR-NEONATAL

DOI: 10.1038/jp.2010.10

AB: OBJECTIVE: To determine if enteral protein and energy supplementation would significantly improve weight gain as compared with energy supplementation alone in ≤ 1250 g infants. STUDY DESIGN: Inclusion criteria were birth weight (BW) ≤ 1250 g, postnatal age ≥ 14 days, diet of $\geq 75\%$ enteral nutrition (fortified human milk or formula) and either failure to regain BW or weight gain < 15 g kg^{-1} per days. Infants were randomized to a multinutrient supplement that provided increased protein and energy (P/E) intake or energy alone (medium chain triglyceride oil, MCT). Growth rates were compared at the end of the 4-week study period. RESULT: Of 30 eligible infants, 23 were enrolled, 12 received MCT (BW=862 \pm 252 g, mean \pm s.d.) and 11 received P/E (BW=879 \pm 241 g). Significantly higher protein intake (P/E=3.5 \pm 0.3 g kg^{-1} per day, MCT=3.0 \pm 0.5 g kg^{-1} per day) and better growth (P/E=17.0 \pm 2.4 g kg^{-1} per day, MCT=11.5 \pm 4.8 g kg^{-1} per day) were observed in the P/E group. CONCLUSION: These data are consistent with the importance of providing additional daily protein intake to achieve increased postnatal growth in very low birth weight infants experiencing slow growth.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/437/CN-00767437/frame.html>

Record #188 of 370



ID: CN-00752120

AU: Arató E

AU: Kürthy M

AU: Sínay L

AU: Kasza G

AU: Menyhei G

AU: Hardi P

AU: Masoud S

AU: Ripp K

AU: Szilágyi K

AU: Takács I

AU: Miklós Z

AU: Bátor A

AU: Lantos J

AU: Kollár L

AU: Roth E

AU: Jancsó G

TI: Effect of vitamin E on reperfusion injuries during reconstructive vascular operations on lower limbs.

SO: Clinical hemorheology and microcirculation

YR: 2010

VL: 44

NO: 2

PG: 125-36

PM: PUBMED 20203367

PT: Journal Article; Randomized Controlled Trial

KY: Antioxidants [administration & dosage];Constriction, Pathologic [surgery];Glutathione [blood];Ischemia [surgery];Leukocytes [metabolism];Lipid Peroxidation [drug effects];Lower Extremity [blood supply];Malondialdehyde [blood];Oxidative Stress [drug effects];Preoperative Care;Prospective Studies;Reperfusion Injury [blood] [drug therapy];Superoxide Dismutase [blood];Vascular Surgical Procedures [methods];Vitamin E [administration & dosage];Humans[checkword]

CC: SR-PVD

AB: INTRODUCTION: The challenge against reperfusion injury and tissue oxidative stress, especially in vascular surgical interventions has an essential importance to reach the optimal clinical result. Numerous experimental attempts have proved the positive antioxidant effect of vitamin E in both chronic and acute phase models. In our study we monitored the effect of continuous preoperative treatment with vitamin E, on oxidative stress and tissue inflammation reactions developed after reconstructive operations. **PATIENTS AND METHODS:** 32 patients have been involved in a randomized, prospective study, all suffering from AFS occlusion proved by angiography, and all undergone supragenual reconstruction. Duration of ischemia and amount of tissues under vascular clamping were almost the same in all patients. In the group treated with E-vitamin, we administered 1 x 200 mg of vitamin E p/o from the preoperative day till the 7th post operative day. Patients of the second group did not receive vitamin E. **MATERIALS AND METHODS:** Peripheral blood samples were collected immediately before operation and at the end of the second reperfusion hour (early reperfusion period). Late reperfusion period has been monitored by analyzing blood samples taken at 24th hour and 7th day next to the operative ischemia. Among oxidative stress parameters, direct measurement of reactive oxygen intermediary (ROI) and determination of antioxidant state (GSH, Total-SH group, SOD) have been performed. Malondialdehyde was chosen as marker for lipidperoxidation. Inflammation reactions were monitored up on expression of adhesion molecules (CD11a and CD18). We also controlled the oscillation of myeloperoxidase (MPO) activity. **RESULTS:** Our study has proved that preoperative (from the preoperative day till the 7th post operative day) administration of 200 mg vitamin E could reduce the level of oxidative stress developed after ischemic-reperfusion insult (lipidproxidation, antioxidant enzymes). According to our results, the prooxidant-antioxidant imbalance also diminished in the group with E-vitamin treatment. We proved that elective administration of vitamin E could decrease the WBC activity (MPO activity, free radicals production, expression of adhesion molecules) and its consequential local inflammation process, during early reperfusion.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/120/CN-00752120/frame.html>

Record #189 of 370



ID: CN-00750778

AU: Birzniece V

AU: Meinhardt U

AU: Gibney J

AU: Johannsson G

AU: Baxter RC

AU: Seibel MJ

AU: Ho KK

TI: Modulatory effect of raloxifene and estrogen on the metabolic action of growth hormone in hypopituitary women.

SO: Journal of clinical endocrinology and metabolism

YR: 2010

VL: 95

NO: 5

PG: 2099-106

PM: PUBMED 20207825

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Calorimetry, Indirect; Cross-Over Studies; Drug Therapy, Combination; Estradiol [therapeutic use]; Estrogen Replacement Therapy; Human Growth Hormone [blood]; Hypopituitarism [drug therapy]; Insulin-Like Growth Factor Binding Protein 3 [metabolism]; Insulin-Like Growth Factor I [metabolism]; Leucine [metabolism]; Raloxifene [therapeutic use]; Selective Estrogen Receptor Modulators [therapeutic use]; Adult[checkword]; Female[checkword]; Humans[checkword]; Middle Aged[checkword]

DOI: 10.1210/jc.2009-2743

AB: CONTEXT: The metabolic action of GH is attenuated by estrogens administered via the oral route. Selective estrogen receptor modulators lower IGF-I to a lesser degree than 17beta-estradiol in GH-deficient women, and their effect on fat and protein metabolism is unknown.

OBJECTIVE: The aim of the study was to compare the modulatory effects of 17beta-estradiol and raloxifene, a selective estrogen receptor modulator, on the metabolic action of GH.

DESIGN: We conducted an open-label, two-group, randomized, two-period crossover study.

PATIENTS AND INTERVENTION: Ten hypopituitary women received GH therapy alone (0.5 mg/d) and GH plus 17beta-estradiol (E(2); 2 mg/d). Eleven hypopituitary women received GH therapy alone and GH plus raloxifene (R; 60 mg/d). The treatment duration was 1 month, with a 4-wk washout period.

MAIN OUTCOME MEASURES: IGF-I, IGFBP-3, resting energy expenditure, and fat oxidation were quantified by indirect calorimetry. We measured whole body leucine turnover from which leucine rate of appearance and leucine incorporation into protein were estimated. RESULTS: GH significantly stimulated all outcome measures. During GH treatment, addition of R significantly reduced mean IGF-I but not IGFBP-3, whereas E(2) reduced both IGF-I and IGFBP-3 levels. Cotreatment with R but not E(2) significantly attenuated the stimulatory effects of GH on fat oxidation. There was a strong trend ($P = 0.08$) toward a greater reduction in leucine incorporation into protein after R compared to E(2) cotreatment. CONCLUSIONS: The modulatory effects of E(2) and R at therapeutic doses on GH

action are different. R during GH therapy exerts a greater inhibitory effect on lipid oxidation and protein anabolism compared to E(2).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/778/CN-00750778/frame.html>

Record #190 of 370



ID: CN-00734790

AU: Xu H

AU: Perez-Cuevas R

AU: Xiong X

AU: Reyes H

AU: Roy C

AU: Julien P

AU: Smith G

AU: Dadelszen P

AU: Leduc L

AU: Audibert F

AU: Moutquin JM

AU: Piedboeuf B

AU: Shatenstein B

AU: Parra-Cabrera S

AU: Choquette P

AU: Winsor S

AU: Wood S

AU: Benjamin A

AU: Walker M

AU: Helewa M

AU: Dubé J

AU: Tawagi G

AU: Seaward G

AU: Ohlsson A

AU: Magee LA

AU: Olatunbosun F

AU: Gratton R

AU: Shear R

AU: Demianczuk N

AU: Collet JP

AU: Wei S

AU: Fraser WD

TI: An international trial of antioxidants in the prevention of preeclampsia (INTAPP).

SO: American journal of obstetrics and gynecology

YR: 2010

VL: 202

NO: 3

PG: 239.e1-239.e10

PM: PUBMED 20207239

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Antioxidants [therapeutic use];Ascorbic Acid [therapeutic use];Dietary Supplements;Double-Blind Method;Fetal Death [epidemiology];Fetal Membranes, Premature Rupture [epidemiology];Hypertension, Pregnancy-Induced [epidemiology] [prevention & control];Pre-Eclampsia [epidemiology] [prevention & control];Prenatal Care;Risk;Risk Factors;Vitamin E [therapeutic use];Adult[checkword];Female[checkword];Humans[checkword];Pregnancy[checkword]

CC: SR-COMP MED: SR-PREG

DOI: 10.1016/j.ajog.2010.01.050

AB: OBJECTIVE: We sought to investigate whether prenatal vitamin C and E supplementation reduces the incidence of gestational hypertension (GH) and its adverse conditions among high- and low-risk women. STUDY DESIGN: In a multicenter randomized controlled trial, women were stratified by the risk status and assigned to daily treatment (1 g vitamin C and 400 IU vitamin E) or placebo. The primary outcome was GH and its adverse conditions. RESULTS: Of the 2647 women randomized, 2363 were included in the analysis. There was no difference in the risk of GH and its adverse conditions between groups (relative risk, 0.99; 95% confidence interval, 0.78-1.26). However, vitamins C and E increased the risk of fetal loss or perinatal death (nonprespecified) as well as preterm prelabor rupture of membranes. CONCLUSION: Vitamin C and E supplementation did not reduce the rate of preeclampsia or GH, but increased the risk of fetal loss or perinatal death and preterm prelabor rupture of membranes.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/790/CN-00734790/frame.html>

Record #191 of 370



ID: CN-00752978

AU: Mannery YO

AU: Ziegler TR

AU: Park Y

AU: Jones DP

TI: Oxidation of plasma cysteine/cystine and GSH/GSSG redox potentials by acetaminophen and sulfur amino acid insufficiency in humans.

SO: Journal of pharmacology and experimental therapeutics

YR: 2010

VL: 333

NO: 3

PG: 939-47

PM: PUBMED 20207721

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't


KY: Acetaminophen [pharmacology]; Adolescent; Amino Acids, Sulfur [deficiency]; Analgesics, Non-Narcotic [pharmacology]; Chromatography, High Pressure Liquid; Cross-Over

Studies;Cysteine [blood];Cystine [blood];Diet;Double-Blind Method;Eating;Glutathione [metabolism];Oxidation-Reduction;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

DOI: 10.1124/jpet.110.166421

AB: Variations in plasma sulfur amino acid (SAA) pools are associated with disease risks, but little information is available about the factors affecting plasma SAA pools. Drug metabolism by glutathione (GSH) and sulfate conjugation can, in principle, represent a quantitatively important burden on SAA supply. The present study was designed to determine whether therapeutic doses of acetaminophen (APAP) alter SAA metabolism in healthy human adults. A double-blind, crossover design incorporating four treatment periods with diets providing 100% of the recommended dietary allowance (RDA) for SAA without or with APAP (15 mg/kg) and 0% RDA for SAA without or with APAP, in randomized order. After a 3-day equilibration period, chemically defined diets with 100 or 0% RDA for SAA were given for 2 complete days. On day 3, APAP or placebo was given in two successive doses (6-h interval), and timed plasma samples were collected. With SAA intake at 100% RDA, APAP administration oxidized the plasma cysteine/cystine redox potential (E(h)CySS) but not the plasma GSH/GSSG redox potential (E(h)GSSG). The extent of oxidation caused by APAP was similar to that seen with 0% SAA and no APAP. However, APAP administration with 0% SAA did not cause further oxidation beyond APAP or 0% SAA alone. In contrast, an oxidation of the plasma E(h)GSSG was apparent for SAA insufficiency only with APAP. The results suggest a need to evaluate possible effects of APAP in association with SAA insufficiency as a contributing factor in disease risk.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/978/CN-00752978/frame.html>

Record #192 of 370 

ID: CN-00752162

AU: Oszukowska L

AU: Knapska-Kucharska M

AU: Makarewicz J

AU: Lewiński A

TI: The influence of thiamazole, lithium carbonate, or prednisone administration on the efficacy of radioiodine treatment (^{131}I) in hyperthyroid patients.

SO: Endokrynologia Polska

YR: 2010

VL: 61

NO: 1

PG: 56-61


PM: PUBMED 20205105

PT: Controlled Clinical Trial; Journal Article

KY: Drug Administration Schedule;Drug Interactions;Drug Therapy, Combination;Hyperthyroidism [blood] [drug therapy];Iodine Radioisotopes [therapeutic use];Lithium Carbonate [pharmacology];Methimazole [pharmacology];Prednisone [pharmacology];Retrospective Studies;Thyroid Hormones [blood];Treatment Outcome;Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

AB: INTRODUCTION: The effects of selected drugs (see below) on the efficacy of ((131)I) radioiodine therapy were examined. MATERIAL AND METHODS: The study involved 200 hyperthyroid patients, treated with radioactive iodine. They were divided into five groups (40 persons in each). In Group I - patients were administered (131)I and thiamazole; in Group II they were given - (131)I and lithium carbonate; in Group III they were given - (131)I only (the assumed absorbed dose - 150-200 Gy, the same as in Groups I and II, for which Group III was a control group); in Group IV they were given - (131)I and prednisone; and in Group V they were given - (131)I only (250-350 Gy, the same as in Group IV, for which Group V was a control group). Therapeutic results were analyzed after six months based on clinical and hormonal status. The evaluation also included effects of the initial hormonal status on the outcome of (131)I therapy in Groups II and IV (v. respective controls, i.e. Groups III and V); such analysis was not performed in Group I because all the patients in that group were initially hyperthyroid. RESULTS: In 145 patients (72.5%) the therapy with (131)I was effective. In 55 patients (27.5%) the therapy was ineffective. The application of thiamazole during the peritherapeutic period in patients treated with 131I reduced the effectiveness of radioiodine, while lithium carbonate had no effect on the therapy outcome. Prednisone increased the effectiveness of the therapy with (131)I. Normalisation of the initial concentration of TSH was advantageous for the (131)I therapeutic outcome only when the assumed absorbed doses of 150-200 Gy were applied, while being of no avail for doses above 250 Gy. CONCLUSIONS: The present results indicate the necessity of careful analysis of administered drugs in hyperthyroid patients while qualifying them to (131)I therapy. The initial concentration of TSH has no effect on the efficacy of radioiodine therapy in cases where absorbed doses are regarded to be ablative. (Pol J Endocrinol 2010; 61 (1): 56-61).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/162/CN-00752162/frame.html>

Record #193 of 370 

ID: CN-00761409

AU: Zhong H

AU: Guo Z

AU: Wei H

AU: Guo L

AU: Wang C

AU: He Y

AU: Xiong H

AU: Liu S

TI: Synergistic effect of ultrasound and thiazone-PEG 400 on human skin optical clearing in vivo.

SO: Photochemistry and photobiology

YR: 2010

VL: 86

NO: 3

PG: 732-7

PM: PUBMED 20202160

PT: Controlled Clinical Trial; Journal Article; Research Support, Non-U.S. Gov't

KY: Drug Combinations;Drug Compounding [methods];Permeability;Polyethylene Glycols [pharmacology];Skin [drug effects];Spectrum Analysis;Swine;Thiadiazines [pharmacology];Tomography, Optical Coherence;Ultrasonics;Adult[checkword];Animals[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1111/j.1751-1097.2010.00710.x

AB: In this paper, we propose a new physical method in combination with mixed solution of thiazone and polyethylene glycol 400 (thiazone PEG 400 solution) penetration into tissue to assess the skin optical clearing. Four treatments were performed: (1) control group (C); (2) polyethylene glycol 400 (PEG400); (3) 0.25% thiazone (0.25%T); (4) 0.25% thiazone and 5-min ultrasound (0.25%T/SP). The diffuse reflectance spectra and imaging depth of human skin in vivo at different times were measured by spectroscopy and optical coherence tomography (OCT). The optical clearing efficacy of skin was qualitatively and quantitatively analyzed. The

results showed that the diffuse reflectance at 540 nm of samples at 10 min after being treated by 0.25%T/SP decreased by approximately 15.51%, whereas, 0.46%, 4.73% and 5.75% were received in C, PEG400 and 0.25%T, respectively. And at 60 min, the decrease in diffuse reflectance of samples in 0.25%T/SP is about 2.22-fold, 1.20-fold compared with that of the samples in PEG 400 and 0.25%T, at 540 nm, respectively. Simultaneously, 0.25%T/SP results in 41.33% increase in OCT 1/e light penetration depth after 60 min. There was a significant difference in the optical clearing effect on skin between ultrasound-mixed solution of thiazone in combination with PEG 400 and the mixed solution ($P < 0.05$).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/409/CN-00761409/frame.html>

Record #194 of 370



ID: CN-00750646

AU: Ahmed S

AU: Ranchor AV

AU: Crijns HJ

AU: Veldhuisen DJ

AU: Gelder IC

TI: Effect of continuous versus episodic amiodarone treatment on quality of life in persistent atrial fibrillation.

SO: Europace

YR: 2010

VL: 12

NO: 6

PG: 785-91

PM: PUBMED 20200016

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Amiodarone [administration & dosage] [adverse effects];Anti-Arrhythmia Agents [administration & dosage] [adverse effects];Atrial Fibrillation [drug therapy] [prevention & control] [psychology];Drug Administration Schedule;Follow-Up Studies;Health Status;Patient Satisfaction;Quality of Life;Questionnaires;Recurrence [prevention & control];Severity of Illness

Index;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1093/europace/euq049

AB: AIMS: Amiodarone is associated with significant adverse effects. We hypothesized that episodic amiodarone treatment would be associated with better quality of life (QoL) compared with continuous treatment in the prevention of recurrent atrial fibrillation (AF). METHODS AND RESULTS: Quality of life was assessed in 158 patients from the Continuous vs. Episodic Prophylactic Treatment with Amiodarone for the Prevention of AF (CONVERT) study, using the Short Form (SF)-36 health survey and University of Toronto AF Severity Scale (AF severity scale) questionnaires at baseline and 1 year. The episodic group received amiodarone 1 month peri-cardioversion, the continuous group continued amiodarone. Patients were assessed for major adverse events and maintenance of sinus rhythm during follow-up (i.e. no AF recurrences at every follow-up visit). Quality of life (assessed by SF-36 and AF severity scale) was comparable between both treatment groups at baseline and 12 months, with similar incidence rates of major adverse events. Fewer patients in the episodic group had maintenance of sinus rhythm during follow-up [27 (36%) vs. 49 (59%), $P = 0.004$]. In the episodic group, maintenance of sinus rhythm was associated with a significant improvement on four SF-36 subscales and AF severity scale at 12 months. In contrast, in the continuous group no significant differences in QoL were seen between patients with continued maintenance of sinus rhythm compared with those with AF recurrence at the end of follow-up. CONCLUSION: Quality of life was comparable in the episodic and continuous treated group after 12 months of follow-up. Continued maintenance of sinus rhythm was associated with an improvement in QoL in the episodic but not the continuous treated group.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/646/CN-00750646/frame.html>

Record #195 of 370



ID: CN-00767412

AU: Kara C

AU: Resorlu B

AU: Cicekbilek I

AU: Unsal A

TI: Analgesic efficacy and safety of nonsteroidal anti-inflammatory drugs after transurethral resection of prostate.

SO: International braz j urol

YR: 2010

VL: 36

NO: 1

PG: 49-54

PM: PUBMED 20202235

PT: Comparative Study; Journal Article; Randomized Controlled Trial

KY: Acetaminophen [administration & dosage] [contraindications]; Anti-Inflammatory Agents, Non-Steroidal [administration & dosage] [contraindications]; Diclofenac [administration & dosage] [contraindications]; Pain Measurement; Pain, Postoperative [drug therapy]; Prospective Studies; Transurethral Resection of Prostate [methods]; Aged[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

AB: OBJECTIVES: The aim of this study was to assess the analgesic efficacy and safety of nonsteroidal anti-inflammatory drugs (NSAIDs), administered as intramuscular diclofenac in comparison with intravenous paracetamol after transurethral resection of the prostate (TURP). MATERIALS AND METHODS: Fifty men, aged 55 to 75 years, undergoing TURP at our hospital were included in this study. Patients were divided randomly and prospectively into two groups (25 patients in each group). Group I (NSAID) received 75 mg of diclofenac i.m. at the end of the operation followed by 75 mg of diclofenac i.m. for 24 hours (75 mg x 2 once a day = 150 mg/24 h) postoperatively. The other group (Group II) consisted of patients who received 1g/100 mL i.v. paracetamol 15 minutes twice daily as postoperative analgesia. Postoperative pain scores were evaluated at 30 minutes, 1, 2, 4 and 6 hours after administration of each analgesic, using a visual analogue scale (VAS). Furthermore, preoperative and postoperative hemoglobin (Hb) levels and hemostatic variables (bleeding time, prothrombine time and the international normalized ratio, i.e. the ratio of a patient's prothrombin time to a normal [control] sample) were recorded in all patients. RESULTS: The pain score changes during a 4 hour period between the two groups was similar ($p = 0.162$). Thirty minutes after surgery, pain scores were high (> 3 cm) in both groups and without differences between groups ($p = 0.11$) but 6 hours after surgery, pain scores were significantly higher with paracetamol compared to diclofenac ($p < 0.05$). No significant difference was observed between the groups regarding the amount of resected tissue, operating time, preoperative-postoperative Hb levels and hemostatic variables. In the both groups, no patient required blood transfusion postoperatively. CONCLUSIONS: NSAIDs are not a contraindication to TURP and should be used for the control of postoperative pain if indicated.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/412/CN-00767412/frame.html>



ID: CN-00750528

AU: Colucci M

AU: Cortopassi F

AU: Porto E

AU: Castro A

AU: Colucci E

AU: Iamonti VC

AU: Souza G

AU: Nascimento O

AU: Jardim JR

TI: Upper limb exercises using varied workloads and their association with dynamic hyperinflation in patients with COPD.

SO: Chest

YR: 2010

VL: 138

NO: 1

PG: 39-46

PM: PUBMED 20202941

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Exercise Therapy [methods];Exercise Tolerance [physiology];Follow-Up Studies;Inspiratory Capacity [physiology];Oxygen Consumption [physiology];Prognosis;Prospective Studies;Pulmonary Disease, Chronic Obstructive [physiopathology] [rehabilitation];Total Lung Capacity [physiology];Upper Extremity [physiology];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]


CC: SR-AIRWAYS

DOI: 10.1378/chest.09-2878

AB: BACKGROUND: Increased ventilation during upper limb exercises (ULE) in patients with COPD is associated with dynamic hyperinflation (DH) and a decrease in inspiratory capacity (IC). The best level of ULE load training is still unknown. Our objective was to evaluate the

dynamic hyperinflation development during ULE using three constant workloads. METHODS: This was a prospective, randomized protocol involving 24 patients with severe COPD (FEV(1) < 50%) performing an endurance symptom-limited arm exercise of up to 20 min in an arm cycloergometer with different workloads (50%, 65%, and 80% of the maximal load). Ventilation, metabolic, and lung function variables (static IC pre-exercise and postexercise) were measured. RESULTS: DH was observed during exercises with 65% (-0.23 L) and 80% (-0.29 L) workloads (P < .0001). Total time of exercise with 80% workload (7.6 min) was shorter than with 50% (12.5 min) (P < .0005) and with 65% (10.1 min; not significant). Oxygen consumption percent predicted (VO(2)) (P < .01) was lower with 50% workload than with 80%. Eighty percent workload showed lower work efficiency (VO(2) [mL/kg]/exercise time) than the other two workloads (P < .0001). CONCLUSION: Different workloads during upper limb exercises showed a direct influence over dynamic hyperinflation and the endurance exercise duration.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/528/CN-00750528/frame.html>

Record #197 of 370 

ID: CN-00761401

AU: Lu Q

AU: Stanton AL

TI: How benefits of expressive writing vary as a function of writing instructions, ethnicity and ambivalence over emotional expression.

SO: Psychology & health

YR: 2010

VL: 25

NO: 6

PG: 669-84

PM: PUBMED 20204944

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adolescent;Asian Americans;Ethnic Groups;Expressed Emotion;Internal-External Control;Treatment


Outcome;Writing;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

CC: SR-COMP MED: SR-DEPRESSN

DOI: 10.1080/08870440902883196

AB: Written emotional disclosure has been reported to confer a variety of benefits on physical and psychological well-being. However, variable findings suggest that outcomes may vary systematically as a function of specific parameters of the experimental design. This study aims to investigate the unique and combined effects of disclosure instructions focusing on emotional expression and instructions facilitating cognitive reappraisal and to examine how ambivalence over emotional expression and ethnicity moderate the effects of these writing instructions. Seventy-one Asian and 59 Caucasian undergraduates (N = 130) with at least minimal physical or depressive symptoms were randomly assigned to one of the four writing conditions: emotional disclosure (ED), cognitive reappraisal (COG), the combination of ED and COG, or a control condition. Self-reported physical symptoms, positive affect (PA) and negative affect were assessed at baseline and three follow-ups spanning 4 months. Mixed linear models revealed that COG writing reduced physical symptoms, ED buffered a decrease in PA over time, and the combination of ED and COG (i.e. self-regulation; SR) was most effective. Asians and highly ambivalent participants benefited most from expressive writing. Findings contribute to the development of a SR moderator model and carry implications for designing expressive disclosure studies, particularly for ethnic minorities.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/401/CN-00761401/frame.html>

Record #198 of 370 

ID: CN-00750941

AU: Wal MH

AU: Jaarsma T

AU: Moser DK

AU: Gilst WH

AU: Veldhuisen DJ

TI: Qualitative examination of compliance in heart failure patients in The Netherlands.

SO: Heart & lung

YR: 2010

VL: 39

NO: 2

PG: 121-30

PM: PUBMED 20207272

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Counseling;Fear;Heart Failure [epidemiology] [psychology] [therapy];Interviews as Topic;Life Style;Motivation;Netherlands [epidemiology];Patient Compliance;Patient Education as Topic;Qualitative Research;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1016/j.hrtlng.2009.07.008

AB: BACKGROUND: Noncompliance with pharmacological and nonpharmacological recommendations is a problem in many heart failure (HF) patients, leading to worse symptoms and readmission. Although knowledge is available regarding factors related to compliance with HF regimens, little is known about patients' perspectives. We investigated patients' reasons and motivations for compliance with HF regimens from their perspective, and we studied how patients manage these recommendations in daily life. The health belief model was used as a framework for this study. METHODS: A qualitative descriptive study was used, and 15 HF patients were interviewed about reasons for compliance, barriers to compliance, interventions that helped them comply with medications, sodium restriction, fluid restriction, and daily weighing. RESULTS: The most commonly reported reasons for compliance included fear of hospitalization and HF symptoms. Barriers to compliance were mainly related to the negative aspects of a regimen, e.g., taste of the food and thirst. Most patients tried to make their lifestyle changes part of the daily routine. Several problems and misunderstandings with the regimen were evident. Patients themselves offered many tips that helped them comply with the regimen. CONCLUSIONS: To improve compliance in HF patients, patient-tailored interventions must be targeted at specific problems and patients' beliefs regarding the regimen, and aim at implementing the regimen into daily life. Healthcare providers need to emphasize the benefits of compliance, motivate patients to comply, and focus on individual barriers to compliance, knowledge deficits, and misunderstandings regarding the regimen. More specific advice about medications and diet is needed. Group interventions, including tips patients themselves provide, might also be useful in helping patients implement the HF regimen in their daily lives.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/941/CN-00750941/frame.html>

Record #199 of 370



ID: CN-00753167

AU: Matusik P

AU: Ma?ecka-Tendera E

AU: Franek E

AU: Januszek-Trzciakowska A

TI: Bone mineral density and metabolism in levothyroxine-treated adolescent girls with euthyroid diffuse goiter.

SO: Endokrynologia Polska

YR: 2010

VL: 61

NO: 1

PG: 14-9

PM: PUBMED 20205099


PT: Controlled Clinical Trial; Journal Article

KY: Adolescent;Bone Density [drug effects];Bone and Bones [metabolism];Goiter [drug therapy] [metabolism];Lumbar Vertebrae [metabolism];Parathyroid Hormone [blood];Thyrotropin [blood];Thyroxine [pharmacology];Child[checkword];Female[checkword];Humans[checkword]

CC: SR-MUSKEL

AB: INTRODUCTION: Bone and mineral metabolism is influenced by thyroid hormones, and levothyroxine (LT(4)) therapy may be associated with reduced bone mass in postmenopausal women. MATERIAL AND METHODS: The aim of the study was to assess the influence of one year of LT(4) treatment in a group of 21 adolescent girls with euthyroid diffuse goiter. Lumbar (L(2)-L(4)) and total body bone mineral density (TOBMD) (Lunar - DXA), serum PTH, osteocalcin, bone alkaline phosphatase, vitamin D(3), calcium, and phosphorus levels and urinary excretion of Ca, P, and hydroxyproline were measured before and after one year of combined LT(4) and iodine treatment. RESULTS: Patients were matched for age, sex, BMI, and maturation status, with controls treated with iodine only. Markers of bone turnover changed in a similar manner in both groups. There was no significant difference in TOBMD value after one year of therapy between LT(4) treated group and controls. Densitometric lumbar spine parameters increased significantly after 12 months in both groups, with no significant differences between them. CONCLUSION: It can be concluded that one year of LT(4) treatment of adolescent girls with euthyroid diffuse goiter does not have a negative impact on their bone remodelling and metabolism. (Pol J Endocrinol 2010; 61 (1): 14-19).

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/167/CN-00753167/frame.html>

Record #200 of 370 

ID: CN-00789931

AU: Zisser H

AU: Wagner R

AU: Pleus S

AU: Haug C

AU: Jendrike N

AU: Parkin C

AU: Schweitzer M

AU: Freckmann G

TI: Clinical performance of three bolus calculators in subjects with type 1 diabetes mellitus: A head-to-head-to-head comparison.

SO: Diabetes technology & therapeutics

YR: 2010

VL: 12

NO: 12

PG: 955-61

XR: EMBASE 2010683762

PT: Journal: Article

KY: adult // article // blood glucose monitoring // clinical article // clinical trial // controlled clinical trial // controlled study // crossover procedure // *dose calculation // equipment design // female // glucose blood level // human // hyperglycemia/dt [Drug Therapy] // hyperglycemia/pc [Prevention] // hypoglycemia/si [Side Effect] // *insulin dependent diabetes mellitus/dt [Drug Therapy] // *insulin pump // intermethod comparison // male // postprandial state // priority journal // prospective study // test meal // glucose/ec [Endogenous Compound] // *insulin/ae [Adverse Drug Reaction] // *insulin/dt [Drug Therapy]

DOI: 10.1089/dia.2010.0064

AB: Background: Insulin pump systems now provide automated bolus calculators (ABCs) that electronically calculate insulin boluses to address carbohydrate intake and out-of-range blood glucose (bG) levels. We compared the efficacy of three ABCs (Accu-Chek Combo [Roche Insulin Delivery Systems (IDS), Inc., Fishers, IN, a member of the Roche Group], Animas 2020 [Animas Corp., West Chester, PA, a Johnson and Johnson company], and MiniMed Paradigm Bolus

Wizard [Medtronic MiniMed, Northridge, CA]) to safely reduce postprandial hyperglycemia in type 1 diabetes mellitus (T1DM). Methods: T1DM subjects (n = 24) were recruited at a single center for a prospective, triple crossover study. ABCs with the programmed target range (80-140 mg/dL) were used in random order. Postprandial hyperglycemia was induced by reducing the calculated bolus by 25%. Two hours after test meals, the ABCs were allowed to determine whether a correction bolus was needed. Differences between 6-h bG values after test meals that achieved 2-h postprandial hyperglycemia and the mean of the target range (110 mg/dL) were determined. Results: The mean difference between 6-h bG levels following test meals and the 110 mg/dL bG target with the MiniMed device (47.4 + 31.8 mg/dL) was significantly higher than the Animas (17.3 + 30.9 mg/dL) and Roche IDS (18.8 + 33.8 mg/dL) devices (P = 0.0022 and P = 0.0049, respectively). The number of meals with 2-h postprandial hyperglycemia and bG levels at 2 h was similar. Roche IDS and Animas devices recommended correction boluses significantly (P = 0.0001 and P = 0.0002, respectively) more frequently than the MiniMed device. ABC use was not associated with severe hypoglycemia. There was no significant difference in the rate of mild hypoglycemia (bG <60 mg/dL not requiring assistance) among the three groups (Roche IDS and Animas, n = 2; MiniMed, n = 0). Conclusions: In this study, the Roche IDS and Animas devices were more efficacious in controlling postprandial hyperglycemia than the MiniMed device. This may be due, in part, to differences in ABC setup protocols and algorithms. Use of ABCs can assist in controlling postprandial glycemia without significant hypoglycemia. Copyright 2010, Mary Ann Liebert, Inc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/931/CN-00789931/frame.html>

Record #201 of 370



ID: CN-00751045

AU: Oikawa Y

AU: Matsuno S

AU: Yajima J

AU: Nakamura M

AU: Ono T

AU: Ishiwata S

AU: Fujimoto Y

AU: Aizawa T

TI: Effects of treatment with once-daily nifedipine CR and twice-daily benidipine on prevention of symptomatic attacks in patients with coronary spastic angina pectoris-Adalat Trial vs Coniel in Tokyo against Coronary Spastic Angina (ATTACK CSA).

SO: Journal of cardiology

YR: 2010

VL: 55

NO: 2

PG: 238-47

PM: PUBMED 20206078


PT: Comparative Study; Journal Article; Randomized Controlled Trial

KY: Acetylcholine;Angina Pectoris [prevention & control];Blood Pressure [drug effects];Coronary Vasospasm [chemically induced] [prevention & control];Dihydropyridines [administration & dosage];Electrocardiography, Ambulatory;Ergonovine;Heart Rate [drug effects];Nifedipine [administration & dosage];Nitrates [therapeutic use];Vasodilator Agents [administration & dosage];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1016/j.jjcc.2009.11.005

AB: BACKGROUND: We compared the efficacy of once-daily treatment with nifedipine CR 40 mg (NR) and twice-daily treatment with benidipine 4 mg (BD) in patients with coronary spastic angina (CSA) registered in 3 cardiovascular institutes in Tokyo. METHODS AND RESULTS: CSA was diagnosed by an ischemic ST change during Holter ECG monitoring or drug-induced test. Thirty patients were randomly allocated to either NR or BD group. The number of symptomatic attacks and the total frequency of short-acting nitrates were examined based on the data in diaries written by patients. There were no significant differences in the baseline characteristics between the two groups. The median number (25-75% quartile) of attacks per week was significantly decreased in NR group, i.e., 1.0 (0.8-2.0) at baseline, 0.0 (0.0-1.0) after 4 weeks of treatment, and 0.0 (0.0-0.0) after 8 weeks of treatment ($P=0.0093$, $P=0.0002$, Wilcoxon's rank-sum test). No significant decrease was observed in BD, i.e. 1.0 (0.5-2.0) at baseline, 1.3 (0.0-3.0) after 4 weeks, and 0.0 (0.0-1.0) after 8 weeks. The number of attacks was fewer in NR than in BD group ($P=0.074$, $P=0.015$, U-test for difference). CONCLUSION: Once-daily treatment with NR 40 mg was more effective than twice-daily treatment with BD in the prevention of CSA attacks.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/045/CN-00751045/frame.html>

Record #202 of 370 

ID: CN-00770286

AU: Alves-Neto WC

AU: Guapo VG

AU: Graeff FG

AU: Deakin JF

AU: Del-Ben CM

TI: Effect of escitalopram on the processing of emotional faces.

SO: Brazilian journal of medical and biological research = Revista brasileira de pesquisas médicas e biológicas / Sociedade Brasileira de Biofísica ... [et al.]

YR: 2010

VL: 43

NO: 3

PG: 285-9

PM: PUBMED 20209375

PT: Journal Article; Randomized Controlled Trial

KY: Citalopram [pharmacology]; Cross-Over Studies; Double-Blind Method; Expressed Emotion [drug effects]; Facial Expression; Pattern Recognition, Visual [drug effects]; Serotonin Uptake Inhibitors [pharmacology]; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Young Adult[checkword]

AB: Serotonin has been implicated in the neurobiology of depressive and anxiety disorders, but little is known about its role in the modulation of basic emotional processing. The aim of this study was to determine the effect of the selective serotonin reuptake inhibitor, escitalopram, on the perception of facial emotional expressions. Twelve healthy male volunteers completed two experimental sessions each, in a randomized, balanced order, double-blind design. A single oral dose of escitalopram (10 mg) or placebo was administered 3 h before the task. Participants were presented to a task composed of six basic emotions (anger, disgust, fear, happiness, sadness, and surprise) that were morphed between neutral and each standard emotion in 10% steps. Escitalopram facilitated the recognition of sadness and inhibited the recognition of happiness in male, but not female faces. No drug effect on subjective measures was detected. These results confirm that serotonin modulates the recognition of emotional faces, and suggest that the gender of the face can have a role in this modulation. Further studies including female volunteers are needed.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/286/CN-00770286/frame.html>

Record #203 of 370



ID: CN-00770289

AU: Englert H

AU: Müller-Nordhorn J

AU: Seewald S

AU: Sonntag F

AU: Völler H

AU: Meyer-Sabellek W

AU: Wegscheider K

AU: Windler E

AU: Katus H

AU: Willich SN

TI: Is patient self-report an adequate tool for monitoring cardiovascular conditions in patients with hypercholesterolemia?

SO: Journal of public health (Oxford, England)

YR: 2010

VL: 32

NO: 3

PG: 387-94

PM: PUBMED 20208067

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Cardiovascular Diseases [diagnosis];Germany;Health Status;Hypercholesterolemia;Medical Records;Physicians, Family;Questionnaires;Reproducibility of Results;Self Disclosure;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1093/pubmed/fdq013

AB: BACKGROUND: To determine the accuracy of patient self-reports of specific cardiovascular diagnoses and to identify individual patient characteristics that influence the accuracy.

METHODS: This investigation was conducted as a part of the randomized controlled ORBITAL study. Patients with hypercholesterolemia were enrolled in 1961 primary-care centers all over Germany. Self-reported questionnaire data of 7640 patients were compared with patients' case report forms (CRFs) and medical records on cardiovascular diseases, using kappa statistics and binomial logit models. **RESULTS:** kappa values ranged from 0.89 for diabetes to 0.04 for angina. The percentage of overreporting varied from 1% for diabetes to 17% for angina, whereas the percentage of underreporting varied from 8.0% for myocardial infarction to 57% for heart failure. Individual characteristics such as choice of individual general practitioner, male gender and age were associated with the accuracy of self-report data. **CONCLUSION:** Since the agreement between patient self-report and CRFs/medical records varies with specific cardiovascular diagnoses in patients with hypercholesterolemia, the adequacy of this tool seems to be limited. However, the authors recommend additional data validation for certain patient groups and consideration of individual patient characteristics associated with over- and underreporting.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/289/CN-00770289/frame.html>

Record #204 of 370 

ID: CN-00763055

AU: Rosen NO

AU: Knäuper B

AU: Dio P

AU: Morrison E

AU: Tabing R

AU: Feldstain A

AU: Amsel R

AU: Mayrand MH

AU: Franco EL

AU: Rosberger Z

TI: The impact of intolerance of uncertainty on anxiety after receiving an informational intervention about HPV: a randomised controlled study.

SO: Psychology & health

YR: 2010

VL: 25

NO: 6

PG: 651-68

PM: PUBMED 20204959

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alphapapillomavirus;Anxiety;Canada;Information Dissemination;Papillomavirus Infections [prevention & control] [psychology];Patient Education as Topic;Uncertainty;Uterine Cervical Neoplasms [psychology];Adult[checkword];Female[checkword];Humans[checkword];Middle Aged[checkword]

DOI: 10.1080/08870440902822913

AB: This study examined the impact of intolerance of uncertainty (IU) and an informational intervention about human papillomavirus (HPV) infection on perceived uncertainty about one's HPV testing status (referred to as 'HPV uncertainty') and anxiety. IU, HPV uncertainty and other pre-intervention measures were assessed through mailed questionnaires. Participants were then randomly assigned to receive either a long (N = 125) or short (N = 124) HPV-specific information pamphlet or a long (N = 131) or short (N = 115) control pamphlet about cancer prevention. Participants subsequently completed measures of HPV uncertainty and anxiety. Providing a lot of HPV information increased HPV uncertainty more than providing little HPV information and cancer prevention information. Among women who received the long HPV or the short control pamphlet, those with higher IU were more anxious than those with lower IU. Women with higher IU are more likely to seek HPV information, but they may also be at risk for experiencing higher anxiety because factual uncertainties about HPV cannot be resolved through the provision of more information.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/055/CN-00763055/frame.html>

Record #205 of 370



ID: CN-00770298

AU: Giancesello L

AU: Pavoni V

AU: Coppini R

AU: Buoninsegni LT

AU: Gori G

AU: Mori E

AU: Paparella L

AU: Gritti G

TI: Comfort and satisfaction during axillary brachial plexus block in trauma patients: comparison of techniques.

SO: Journal of clinical anesthesia

YR: 2010

VL: 22

NO: 1

PG: 7-12

PM: PUBMED 20206845

PT: Comparative Study; Journal Article; Randomized Controlled Trial

KY: Anesthetics, Local; Arm Injuries [surgery]; Axilla; Brachial Plexus; Bupivacaine; Electric Stimulation Therapy [methods]; Fractures, Bone [surgery]; Lidocaine; Nerve Block [methods]; Patient Satisfaction; Prospective Studies; Aged[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

DOI: 10.1016/j.jclinane.2009.02.010

AB: STUDY OBJECTIVE: To investigate the comfort and satisfaction of patients with trauma of the upper limb during two different techniques of axillary brachial plexus block, electrical nerve stimulation and fascial pop. DESIGN: Randomized-prospective, observational study. SETTING: University surgical center. PATIENTS: 100 ASA physical status I and II patients undergoing surgery for trauma of the hand and forearm. INTERVENTIONS: Patients received axillary brachial plexus block with a mixture of 0.5% bupivacaine and 2% lidocaine. They were then allocated to one of two groups to receive either electrical nerve stimulation (Group 1, n = 50), or fascial pop technique (Group 2, n = 50) for nerve location. MEASUREMENTS: Data were collected on patient demographics, surgery, frequency of complications, and sedation required during the block. Discomfort during the block and surgical comfort were quantified by visual analog scale (0-10). Satisfaction was determined by the following scale: very satisfied, satisfied, dissatisfied, and very dissatisfied. Patients also indicated if in the future they would like to

receive the same method of anesthesia. MAIN RESULTS: No differences in demographic or surgical data were found. No serious complications were observed. Eighteen Group 1 patients (36%) and none in Group 2 needed sedation during the blocks. Discomfort during the procedures was greater in Group 1 than Group 2 (4.5 ± 1.2 vs 1.5 ± 1 , $P < 0.05$), while patients reported good surgical comfort with both techniques (2.4 ± 2.9 vs 2.2 ± 2.1 , NS). Eighteen patients in Group 1 and 48 patients in Group 2 would accept the same block for future surgery. CONCLUSIONS: In trauma patients, the fascial pop technique is effective, reduces sedation during axillary brachial plexus block, and has a higher patient acceptance rate than the electrical nerve stimulation technique.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/298/CN-00770298/frame.html>

Record #206 of 370



ID: CN-00761388

AU: Santos Dde O

AU: Martins MC

AU: Cipriano SL

AU: Pinto RM

AU: Cukier A

AU: Stelmach R

TI: Pharmaceutical care for patients with persistent asthma: assessment of treatment compliance and use of inhaled medications.

SO: Jornal brasileiro de pneumologia : publicaça?o oficial da Sociedade Brasileira de Pneumologia e Tisilogia

YR: 2010

VL: 36

NO: 1

PG: 14-22

PM: PUBMED 20209303


PT: Controlled Clinical Trial; Journal Article

KY: Adolescent;Analysis of Variance;Anti-Asthmatic Agents [administration & dosage];Asthma [drug therapy];Medication Adherence [statistics & numerical data];Metered Dose Inhalers;Patient Education as Topic [standards];Pharmaceutical Services [standards];Powders;Prospective Studies;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

CC: SR-AIRWAYS

AB: OBJECTIVE: To evaluate treatment compliance and use of inhaled medications of patients with asthma receiving complementary pharmaceutical care. METHODS: A controlled prospective parallel study involving a study group and a control group. We selected 60 patients with persistent asthma and using metered-dose inhalers (MDIs), dry powder inhalers (DPIs) or both. The patients were evaluated three times over 60 days. Instructions were provided to the patients in the study group at all visits but only at the first visit to those in the control group. The patients using < 80% or > 120% of the total number of prescribed doses were classified as noncompliant. The inhalation technique was quantified by a scoring system. A satisfactory technique was defined as a score higher than 7 (maximum, 9) for MDIs and higher than 4 (maximum, 5) for DPIs. RESULTS: The final study sample comprised 28 study group patients and 27 control group patients, of whom 18 (64.3%) and 20 (74.7%), respectively, were considered treatment compliant. From the first to the third visits, there were increases, in the study and control groups, in the median MDI-use score (from 3 [range, 0-5] to 8 [range, 8-9]; $p < 0.001$; and from 5 [range, 2-6] to 7 [range, 6-8]), as well as in the median DPI-use score (from 3 [range, 2-4] to 5 [range, 4-5] and from 3 [range, 2-4] to 4 [range, 3-5]). CONCLUSIONS: The counseling provided by the pharmacist to the patient was important to assist in the implementation of the appropriate inhalation technique, especially for MDI use.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/388/CN-00761388/frame.html>

Record #207 of 370 

ID: CN-00751056

AU: Roussi P

AU: Sherman KA

AU: Miller S

AU: Buzaglo J

AU: Daly M

AU: Taylor A

AU: Ross E

AU: Godwin A

TI: Enhanced counselling for women undergoing BRCA1/2 testing: Impact on knowledge and psychological distress-results from a randomised clinical trial.

SO: Psychology & health

YR: 2010

VL: 25

NO: 4

PG: 401-15

PM: PUBMED 20204945

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, Non-P.H.S.

KY: BRCA1 Protein [genetics];BRCA2 Protein [genetics];Breast Neoplasms [genetics];Genetic Counseling [methods];Genetic Predisposition to Disease;Genetic Testing [psychology];Health Knowledge, Attitudes, Practice;Mutation [genetics];Ovarian Neoplasms [genetics];Female[checkword];Humans[checkword];Middle Aged[checkword]

CC: SR-BREASTCA

DOI: 10.1080/08870440802660884

AB: This randomised controlled trial evaluated the impact of an enhanced counselling (EC) intervention on knowledge about the heritability of breast and ovarian cancer and distress, as a function of BRCA test result, among high-risk women. Before deciding about whether or not to undergo genetic testing, participants were randomly assigned to the EC intervention (N = 69), designed to promote cognitive and affective processing of cancer risk information (following the standard individualised counselling session), or to the control condition (N = 65), which involved standard individualised counselling followed by a general health information session to control for time and attention. Women in the EC group exhibited greater knowledge than women in the control group, 1 week after the intervention. Further, at the affective level, the intervention was found to be the most beneficial for women testing positive: specifically 1 week after test result disclosure, women in the intervention group who tested positive experienced lower levels of distress than women in the control group who tested positive. The findings suggest that the design of counselling aids should include a component that explicitly activates the individual's cognitive-affective processing system.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/056/CN-00751056/frame.html>

Record #208 of 370



ID: CN-00750637

AU: Jab?onowski Z

AU: Kedzierski R

AU: Mieko? E

AU: Sosnowski M

TI: Comparison of neodymium-doped yttrium aluminum garnet laser treatment with cold knife endoscopic incision of urethral strictures in male patients.

SO: Photomedicine and laser surgery

YR: 2010

VL: 28

NO: 2

PG: 239-44

PM: PUBMED 20201661

PT: Comparative Study; Journal Article; Randomized Controlled Trial

KY: Lasers, Solid-State [therapeutic use];Urethra [surgery];Urethral Stricture [surgery];Urologic Surgical Procedures [methods];Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-INCONT

DOI: 10.1089/pho.2009.2516

AB: OBJECTIVE: To assess the effectiveness of visual laser ablation treatment with neodymium-doped yttrium aluminum garnet (Nd:YAG) laser in male patients with urethral strictures and to compare the effects with those obtained in patients treated with Sachse's optical urethrotomy. MATERIALS AND METHODS: Fifty patients aged 22 to 83 (mean age 61.8) with primary (n = 26, 52%) and recurrent (n = 24, 48%) urethral strictures 0.3 to 2.4 cm long qualified for the study. The patients were randomized into two groups: 30 men treated using visual laser ablation of urethral strictures (VLASU) with Nd:YAGlaser and 20 men treated by correction of urethral strictures using Sachse's optical urethrotomy. RESULTS: At 12-month follow-up, seven (35%) patients who underwent optical urethrotomy and 21 (70%) in the VLASU group did not require repetition of the procedure. The choice of VLASU as a method of treatment significantly decreased the probability of therapeutic failure and recurrence of urethral strictures (p = 0.02). CONCLUSION: VLASU can be used as a method of treatment of

this disorder. It is an effective, modern, low-invasive, and repeatable technique and is technically simple and easy to master. It can be used in cases in which introduction of a 22 Char optical urethrotome into the stricture site is impossible, as well as for treatment of multiple strictures during one procedure.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/637/CN-00750637/frame.html>

Record #209 of 370



ID: CN-00729593

AU: Keenan JD

AU: Lakew T

AU: Alemayehu W

AU: Melese M

AU: Porco TC

AU: Yi E

AU: House JI

AU: Zhou Z

AU: Ray KJ

AU: Acharya NR

AU: Whitcher JP

AU: Gaynor BD

AU: Lietman TM

TI: Clinical activity and polymerase chain reaction evidence of chlamydial infection after repeated mass antibiotic treatments for trachoma.

SO: American journal of tropical medicine and hygiene

YR: 2010

VL: 82

NO: 3

PG: 482-7

PM: PUBMED 20207878

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Adolescent; Anti-Bacterial Agents [therapeutic use]; Azithromycin [therapeutic use]; Ethiopia [epidemiology]; Polymerase Chain Reaction; Prevalence; Trachoma [drug therapy] [epidemiology] [prevention & control]; Adult[checkword]; Child[checkword]; Child, Preschool[checkword]; Female[checkword]; Humans[checkword]; Infant[checkword]; Male[checkword]; Young Adult[checkword]

CC: SR-EYES

DOI: 10.4269/ajtmh.2010.09-0315

AB: It is unclear how the prevalence of clinically active trachoma correlates with the prevalence of ocular chlamydial infection at the community level. In 24 villages from a cluster-randomized clinical trial of mass azithromycin distributions in Ethiopia, the correlation between the prevalence of clinical activity (on examination) and chlamydial infection (by polymerase chain reaction) was moderately strong before mass antibiotic treatments (Pearson's correlation coefficient $r = 0.75$, 95% confidence interval [CI] = 0.52-0.87), but decreased at each time point during four biannual treatments (at 24 months, $r = 0.15$, 95% CI = -0.14-0.41). One year after the final treatment, the correlation coefficient had increased, but not to the pre-treatment level ($r = 0.55$, 95% CI = 0.30-0.73). In a region with hyperendemic trachoma, conjunctival examination was a useful indicator of the prevalence of chlamydial infection before treatments, less useful during mass treatments, but regained utility by one year after treatments had stopped.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/593/CN-00729593/frame.html>

Record #210 of 370



ID: CN-00752185

AU: Venturelli M

AU: Lanza M

AU: Muti E

AU: Schena F

TI: Positive effects of physical training in activity of daily living-dependent older adults.

SO: Experimental aging research

YR: 2010

VL: 36

NO: 2

PG: 190-205

PM: PUBMED 20209421

PT: Journal Article; Randomized Controlled Trial

KY: Activities of Daily Living;Analysis of Variance;Arm;Assisted Living Facilities;Cognition [physiology];Cognition Disorders [prevention & control];Exercise [physiology];Feasibility Studies;Frail Elderly [statistics & numerical data];Geriatric Assessment [methods] [statistics & numerical data];Motor Activity [physiology];Muscle Strength [physiology];Neuropsychological Tests [statistics & numerical data];Range of Motion, Articular [physiology];Shoulder Joint;Wheelchairs;Aged, 80 and over[checkword];Female[checkword];Humans[checkword]

CC: SR-DEMENTIA

DOI: 10.1080/03610731003613771

AB: The goal of this study was to determinate the effects of physical training in older adults with mobility limitations. Thirty frail women (84 +/- 6 years) were randomly assigned to a training or control group for 12 weeks of upper body physical training (UBT) performed sitting on wheelchairs. Trained subjects showed a significant improvement in arms strength (+29%), and shoulder flexibility (+10 cm) but did not improve in arms circumference. The activities of daily living (ADLs) were improved (+77%), cognitive function as defined by the Mini-Mental State Examination (MMSE) was maintained in the trained group (+3%) and declined in the control group (-21%). These results demonstrate that UBT in dependent older women with mobility limitations can increase strength and improve ADLs.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/185/CN-00752185/frame.html>

Record #211 of 370



ID: CN-00734792

AU: Shahgholi E

AU: Ehsani MA

AU: Salamati P

AU: Maysamie A

AU: Sotoudeh K

AU: Mokhtariazad T

TI: Immunogenicity of trivalent influenza vaccine in children with acute lymphoblastic leukemia during maintenance therapy.

SO: Pediatric blood & cancer

YR: 2010

VL: 54

NO: 5

PG: 716-20

PM: PUBMED 20205258

PT: Controlled Clinical Trial; Journal Article; Research Support, Non-U.S. Gov't


KY: Adolescent;Immunocompromised Host;Influenza A Virus, H1N1 Subtype;Influenza A Virus, H3N2 Subtype;Influenza B virus;Influenza Vaccines [immunology];Influenza, Human [prevention & control] [virology];Iran;Precursor Cell Lymphoblastic Leukemia-Lymphoma [immunology];Vaccines, Combined;Child[checkword];Child, Preschool[checkword];Female[checkword];Humans[checkword];Infant[checkword];Male[checkword]

DOI: 10.1002/pbc.22421

AB: PURPOSE: The aim of this study was to assess the immune response of children with acute lymphoblastic leukemia (ALL) to influenza vaccine and to compare it with healthy controls.

PROCEDURE: Thirty-two children aged 1-18 years with ALL on maintenance therapy and 30 healthy sibling controls were enrolled in the study. All children were vaccinated with trivalent inactivated influenza vaccine. Hemagglutinin-inhibition (HI) antibody titers were determined in sera of both patient and control groups just before and 4 weeks after vaccination. The ability of each group to mount a protective ($>$ or $=40$) and/or fourfold titer was measured. RESULTS: The protective response for virus subunits among patients and healthy controls were 43.4% versus 88% for H1N1 ($P = 0.04$), 63.3% versus 80% for H3N2 antigens ($P = 0.06$), and 26% versus 73% for B antigen ($P = 0.001$). Responses for H1N1 and B subunits were significantly lower in patients than controls. In the patient group, the significant response to each virus was demonstrated in the analysis of pre- and post-vaccination geometric mean titer (GMT) ($P = 0.001$). The percentage of patients and controls with fourfold increase in HI titers were 56.2% versus 80% for H1N1 ($P = 0.04$), 40.6% versus 53.3% for H3N2 ($P = 0.31$), and 59.4% versus 83.3% for B ($P = 0.038$). Immune responses for H1N1 and B subunits were significantly lower in patients than controls. CONCLUSIONS: Influenza vaccine is tolerated well in ALL patients with acceptable but limited immune response compared to healthy controls. These findings support the recommendation for annual influenza vaccination in children with ALL.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/792/CN-00734792/frame.html>

Record #212 of 370 

ID: CN-00779851

AU: Burns A

AU: Mittelman M

AU: Cole C

AU: Morris J

AU: Winter J

AU: Page S

AU: Brodaty H

TI: Transcultural influences in dementia care: observations from a psychosocial intervention study.

SO: Dementia and geriatric cognitive disorders

YR: 2010

VL: 30

NO: 5

PG: 417-23

PM: PUBMED 21071943

PT: Comparative Study; Journal Article; Randomized Controlled Trial

KY: Affect;Alzheimer Disease [therapy];Anxiety [complications] [psychology];Caregivers [psychology];Counseling;Cultural Characteristics;Culture;Dementia [drug therapy] [psychology] [therapy];Depression [complications] [psychology];Follow-Up Studies;Great Britain;Neuropsychological Tests;New South Wales;New York;Nootropic Agents [therapeutic use];Nursing Homes;Psychiatric Status Rating Scales;Quality of Life;Social Support;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1159/000314860

AB: BACKGROUND: Various models of intervention for caregivers of patients with dementia have been described. There has been little direct comparison of cultural differences between countries and the effect any differences may exert on the outcome of caregiver interventions. AIMS: The aims of the three-country study (USA, Australia and the UK) were to assess whether caregiver interventions can still be successful when anti-dementia drugs are provided to patients, and whether a caregiver intervention can be successfully implemented using the same methods in three different English-speaking countries. In this paper, the cultural differences and similarities between the three countries are examined. METHOD: Randomised, controlled trial involving 158 patients and their caregivers (divided equally across three centres, New York, Sydney and Manchester) with all the patients receiving donepezil and the caregivers randomised to a caregiver intervention or treatment as usual. RESULTS: There were few differences between countries in the main outcome measures, and no differences between the treatment-as-usual group and the intervention, but interesting cultural nuances were observed between groups. Despite these differences, the caregiver intervention was associated with positive results on caregiver depression across all the countries. CONCLUSIONS: This first multinational carer intervention study has emphasised the similarities between the three countries whilst highlighting crucial differences which may be important when planning cross-cultural studies in the future. The positive results achieved on caregiver depression were replicated across the three centres.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/851/CN-00779851/frame.html>

Record #213 of 370



ID: CN-00742302

AU: Farlow MR

AU: Alva G

AU: Meng X

AU: Olin JT

TI: A 25-week, open-label trial investigating rivastigmine transdermal patches with concomitant memantine in mild-to-moderate Alzheimer's disease: a post hoc analysis.

SO: Current medical research and opinion

YR: 2010

VL: 26

NO: 2

PG: 263-9

PM: PUBMED 19929593

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Administration, Cutaneous; Algorithms; Alzheimer Disease [drug therapy] [pathology]; Antiparkinson Agents [administration & dosage] [adverse effects]; Cholinesterase Inhibitors [administration & dosage] [adverse effects]; Drug Administration Schedule; Drug Therapy, Combination; Indans [administration & dosage]; Memantine [administration & dosage] [adverse effects]; Neuroprotective Agents [administration & dosage] [adverse effects]; Phenylcarbamates [administration & dosage] [adverse effects]; Piperidines [administration & dosage]; Severity of Illness Index; Time Factors; Treatment Outcome; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1185/03007990903434914

AB: OBJECTIVE: To investigate the tolerability and efficacy of the rivastigmine transdermal patch in patients with mild-to-moderate Alzheimer's disease receiving concomitant memantine. RESEARCH DESIGN AND METHODS: Post hoc analysis of a 25-week, randomized, prospective, open-label, parallel-group study. Patients receiving donepezil were switched to rivastigmine patches (4.6 mg/24 h) immediately or following a 7-day withdrawal for 4 weeks (core phase), before titrating up to 9.5 mg/24 h for a further 20-week extension phase. Prior memantine therapy was continued throughout. MAIN OUTCOME MEASURES: Tolerability (adverse events [AEs], serious AEs [SAEs] and discontinuations) and efficacy (cognition, global functioning and activities of daily living [ADLs]) were assessed for the rivastigmine transdermal patch, with or without concomitant memantine. RESULTS: Overall, 135 and 126 patients received rivastigmine with and without memantine, respectively. Of these, 122 (90.4%) and 118 (93.7%) patients with and without memantine, respectively, completed the core phase; 120 and 114 patients, respectively, entered the extension phase, and 90 (75.0%) and 86 (75.4%) completed the study. The incidences of AEs (73.3 vs. 67.5%) and SAEs (10.4 vs. 7.1%) were both slightly larger in patients receiving concomitant memantine, but the differences were not statistically significant (95% CIs: -5.2, 16.9 and -3.6, 10.1 for AEs and SEAs, respectively). The incidence of gastrointestinal AEs was low in both groups. Discontinuation due to AEs was higher in patients who received memantine (17.0 vs. 11.9%). Changes in cognitive and global function were similar between groups. ADL scores worsened in both groups; significantly more in those treated with memantine. CONCLUSION: Use of the rivastigmine transdermal patch in patients on established memantine appears to be well-tolerated, with only modest, non-significant increases in AEs compared with monotherapy, and did not seem to affect cognition or global functioning adversely.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/302/CN-00742302/frame.html>

Record #214 of 370



ID: CN-00742508

AU: Lauridsen TG

AU: Vase H

AU: Bech JN

AU: Nielsen S

AU: Pedersen EB

TI: Direct effect of methylprednisolone on renal sodium and water transport via the principal cells in the kidney.

SO: European journal of endocrinology / European Federation of Endocrine Societies

YR: 2010

VL: 162

NO: 5

PG: 961-9

PM: PUBMED 20203161

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adolescent;Aldosterone [blood];Angiotensin II [blood];Aquaporin 2 [urine];Atrial Natriuretic Factor [blood];Blood Pressure [drug effects];Cross-Over Studies;Epithelial Sodium Channels [urine];Kidney [drug effects] [physiology];Methylprednisolone [pharmacology];Natriuretic Peptide, Brain [blood];Pulse;Renin [blood];Sodium [urine];Adult[checkword];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1530/EJE-10-0030

AB: BACKGROUND: Glucocorticoids influence renal concentrating and diluting ability. We tested the hypothesis that methylprednisolone treatment increased renal water and sodium absorption by increased absorption via the aquaporin-2 (AQP2) water channels and the epithelial sodium channels (ENaCs) respectively. METHODS: The effect of methylprednisolone was measured during fasting in a randomized, placebo-controlled, single-blinded cross-over

study of 15 healthy humans. The subjects received a standardized diet on day 1, fasted on day 2, and received 500 mg methylprednisolone intravenously on day 3. The effect variables were urinary excretions of AQP2 (u-AQP2), urinary excretion of the beta-fraction of the ENaC (u-ENaC(beta)), cAMP (u-cAMP), prostaglandin E(2) (u-PGE(2)), free water clearance (C(H₂O)), and fractional excretion of sodium (FE(Na)), and plasma vasopressin (p-AVP), angiotensin II (p-Ang II), aldosterone (p-Aldo), atrial natriuretic peptide (p-ANP), and brain natriuretic peptide (p-BNP). RESULTS: Methylprednisolone treatment increased u-AQP2, u-ENaC(beta), and p-AVP significantly, but did not change u-cAMP, c(H₂O), and FE(Na). P-ANP increased during methylprednisolone treatment, but after the increase in u-AQP2 and u-ENaC(beta). U-PGE(2), p-Ang II, and p-BNP were unchanged. Heart rate increased and diastolic blood pressure fell. CONCLUSIONS: Methylprednisolone increased u-AQP2 and u-ENaC. Neither the AVP-cAMP axis nor changes in the renin-angiotensin-Aldo system, or the natriuretic peptide system seems to bear a causal relationship with the increase in either u-AQP2 or u-ENaC. Most probably, the effect is mediated via a direct effect of methylprednisolone on the principal cells. The lack of decrease in urinary output and sodium reabsorption most likely can be attributed to the diuretic and natriuretic properties of the increased secretion of ANP.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/508/CN-00742508/frame.html>

Record #215 of 370



ID: CN-00752186

AU: Diniz DB

AU: Depes Dde B

AU: Pereira AM

AU: David SD

AU: Lippi UG

AU: Baracat FF

AU: Lopes RG

TI: [Pain evaluation in office hysteroscopy: comparison of two techniques].

SO: Revista brasileira de ginecologia e obstetrícia : revista da Federação Brasileira das Sociedades de Ginecologia e Obstetrícia

YR: 2010

VL: 32

NO: 1

PG: 26-32

PM: PUBMED 20209259

PT: Comparative Study; English Abstract; Journal Article; Randomized Controlled Trial

KY: Ambulatory Care;Hysteroscopy [adverse effects];Office Visits;Pain Measurement [methods];Pain, Postoperative [diagnosis] [etiology];Prospective Studies;Adult[checkword];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Middle Aged[checkword];Young Adult[checkword]

CC: SR-MENSTR

AB: PURPOSE: to compare the pain reported by patients submitted to hysteroscopy by the standard technique with carbon dioxide (CO₂) and to vaginal hysteroscopy with physiological saline (0.9% NaCl). METHODS: this was a prospective cohort study conducted at an ambulatory hysteroscopy service. A total of 117 patients with indication for the exam were included, being randomly assigned to one of the groups. All patients answered an epidemiological questionnaire and scored the pain expected before the exam and that felt after the end of the procedure on a verbal pain scale from 0 to 10. A speculum, traction of the cervix, insertion of a 30 masculine light source and a diagnostic shirt with a total diameter of 5 mm were used for the standard technique. The cavity was distended with CO₂ under a pressure of 100 mmHg controlled with a hysteroflator, and a biopsy was obtained with a Novak curette. Vaginoscopy was performed without a touch by distention of the vagina with fluid, direct visualization of the cervix and introduction of the light source with two continuous-flow shirts, with an accessory channel with an oval profile, the whole set measuring 5 mm in diameter. The medium distention was 0.9% NaCl and the pressure used was that considered to be necessary for an adequate visualization of the canal and of the cavity with an external pneumatic pressurizer. The biopsy was obtained in a directed manner using an endoscopic clamp. The mean and standard deviation were calculated for the quantitative variables and the frequency was calculated for the qualitative variables. The Student's t-test was used to compare the means, and the chi-square or exact Fisher test was used (when $n < 5$) for the categorical analysis using the SPSS 15.0 software. The study was designed for a 95% test power, with the level of significance set at $p < 0.05$. RESULTS: the groups were similar regarding age, parity, previous uterine surgeries, menopausal status, and the need for a biopsy. In comparison to the group submitted to the standard technique, the vaginoscopy group involved a lower technical difficulty (5.1 versus 17.2%, $p = 0.03$), a higher rate of exams considered to be satisfactory (98.3 versus 89.7%, $p = 0.04$) and a lower pain index (4.8 versus 6.1; $p = 0.01$), as the difference were more evident when patients who never had a previous normal delivery were compared (4.9 versus 7.1; $p = 0.0001$). When the pain scale was stratified as mild (0-4), moderate (5-7) or intense (8-10), the vaginoscopy technique was found to be associated with a 52% reduction of the frequency of intense pain ($p = 0.005$). CONCLUSIONS: vaginohysteroscopy was proved to be a less painful procedure than the technique based on the use of a speculum and CO₂,

regardless of age, menopause or parity, with more satisfactory results and lower technical difficulty.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/186/CN-00752186/frame.html>

Record #216 of 370



ID: CN-00743675

AU: Lu M

AU: Cohen MH

AU: Rieves D

AU: Pazdur R

TI: FDA report: Ferumoxytol for intravenous iron therapy in adult patients with chronic kidney disease.

SO: American journal of hematology

YR: 2010

VL: 85

NO: 5

PG: 315-9

PM: PUBMED 20201089

PT: Journal Article; Randomized Controlled Trial

KY: Administration, Oral;Anemia, Iron-Deficiency [blood] [drug therapy] [etiology];Drug Approval;Drug Hypersensitivity [etiology];Ferrosoferric Oxide [administration & dosage] [adverse effects];Ferrous Compounds [administration & dosage];Hematinics [administration & dosage] [adverse effects];Hemoglobins [metabolism];Hypotension [chemically induced];Infusions, Intravenous;Kidney Failure, Chronic [complications];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1002/ajh.21656

AB: On June 30, 2009, the United States Food and Drug Administration (FDA) approved ferumoxytol (Feraheme injection, AMAG Pharmaceuticals), an iron-containing product for intravenous (IV) administration, for the treatment of iron deficiency anemia in adult patients

with chronic kidney disease (CKD). The safety and efficacy of ferumoxytol were assessed in three randomized, open-label, controlled clinical trials. Two trials evaluated patients with nondialysis dependent CKD and a third trial assessed patients undergoing hemodialysis. Randomization was either to ferumoxytol or oral iron. Ferumoxytol was administered as two 510 mg IV injections, separated by 3-8 days. Oral iron, Ferro-Sequels, was administered at a dose of 100 mg twice daily for 21 days. In all three clinical trials, ferumoxytol administration increased the mean blood hemoglobin (Hgb) concentrations by approximately 1.0 g/dL over the 35 day period, a mean increase that was greater than what was observed in patients receiving oral iron. Patients receiving ferumoxytol also had increases in blood transferrin saturation (TSAT) and ferritin values. For the proposed ferumoxytol dosing regimen, 4.9% of patients had serum ferritin ≥ 800 ng/mL and TSAT $\geq 50\%$ post-treatment. The most important ferumoxytol safety concerns were hypersensitivity reactions and/or hypotension. Anaphylaxis or anaphylactoid reactions were reported in 0.2% of subjects, and other adverse reactions potentially associated with hypersensitivity (e.g., pruritus, rash, urticaria, or wheezing) were reported in 3.7%. Hypotension was observed in 1.9%, including three patients with serious hypotensive reactions. Ferumoxytol administration may transiently affect the diagnostic ability of magnetic resonance imaging and the drug label provides further information regarding this effect.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/675/CN-00743675/frame.html>

Record #217 of 370



ID: CN-00784530

AU: Johnston V

AU: Walker N

AU: Thomas DP

AU: Glover M

AU: Chang AB

AU: Bullen C

AU: Morris P

AU: Brown N

AU: Vander Hoorn S

AU: Borland R

AU: Segan C

AU: Trenholme A

AU: Mason T

AU: Fenton D

AU: Ellis K

TI: The study protocol for a randomized controlled trial of a family-centred tobacco control program about environmental tobacco smoke (ETS) to reduce respiratory illness in Indigenous infants.

SO: BMC public health

YR: 2010

VL: 10

PG: 114

PM: PUBMED 20205950

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Australia;Clinical Protocols;Double-Blind Method;Environmental Exposure [prevention & control];Family;Follow-Up Studies;New Zealand;Oceanic Ancestry Group;Patient Selection;Population Groups;Research Design;Respiratory Tract Diseases [prevention & control];Sample Size;Smoking Cessation [methods];Tobacco Smoke Pollution [prevention & control];Female[checkword];Humans[checkword];Infant[checkword];Male[checkword]

CC: SR-TOBACCO

DOI: 10.1186/1471-2458-10-114

AB: BACKGROUND: Acute respiratory illness (ARI) is the most common cause of acute presentations and hospitalisations of young Indigenous children in Australia and New Zealand (NZ). Environmental tobacco smoke (ETS) from household smoking is a significant and preventable contributor to childhood ARI. This paper describes the protocol for a study which aims to test the efficacy of a family-centred tobacco control program about ETS to improve the respiratory health of Indigenous infants in Australia and New Zealand. For the purpose of this paper 'Indigenous' refers to Australia's Aboriginal and Torres Strait Islander peoples when referring to Australian Indigenous populations. In New Zealand, the term 'Indigenous' refers to Māori. METHODS/DESIGN: This study will be a parallel, randomized, controlled trial. Participants will be Indigenous women and their infants, half of whom will be randomly allocated to an 'intervention' group, who will receive the tobacco control program over three home visits in the first three months of the infant's life and half to a control group receiving 'usual care' (i.e. they will not receive the tobacco control program). Indigenous health workers will deliver the intervention, the goal of which is to reduce or eliminate infant exposure to ETS. Data collection will occur at baseline (shortly after birth) and when the infant is four months and one year of age. The primary outcome is a doctor-diagnosed, documented case of

respiratory illness in participating infants. DISCUSSION: Interventions aimed at reducing exposure of Indigenous children to ETS have the potential for significant benefits for Indigenous communities. There is currently a dearth of evidence for the effect of tobacco control interventions to reduce children's exposure to ETS among Indigenous populations. This study will provide high-quality evidence of the efficacy of a family-centred tobacco control program on ETS to reduce respiratory illness. Outcomes of our study will be important and significant for Indigenous tobacco control in Australia and New Zealand and prevention of respiratory illness in children.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/530/CN-00784530/frame.html>

Record #218 of 370



ID: CN-00781524

AU: Kärkkäinen M

AU: Tuppurainen M

AU: Salovaara K

AU: Sandini L

AU: Rikkonen T

AU: Sirola J

AU: Honkanen R

AU: Jurvelin J

AU: Alhava E

AU: Kröger H

TI: Effect of calcium and vitamin D supplementation on bone mineral density in women aged 65-71 years: a 3-year randomized population-based trial (OSTPRE-FPS).

SO: Osteoporosis international

YR: 2010

VL: 21

NO: 12

PG: 2047-55

PM: PUBMED 20204604

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Bone Density [drug effects]; Bone Density Conservation Agents [adverse effects] [therapeutic use]; Calcium [adverse effects] [therapeutic use]; Cholecalciferol [adverse effects] [therapeutic use]; Dietary Supplements; Drug Therapy, Combination; Follow-Up Studies; Osteoporosis, Postmenopausal [physiopathology] [prevention & control]; Treatment Outcome; Vitamin D [analogs & derivatives] [blood]; Aged[checkword]; Female[checkword]; Humans[checkword]

CC: SR-COMP MED

DOI: 10.1007/s00198-009-1167-8

AB: SUMMARY: The Osteoporosis Risk Factor and Prevention-Fracture Prevention Study (OSTPRE-FPS) was a randomized population-based open trial (n=?593). The supplementation group (n=?287) received daily cholecalciferol 800 IU + calcium 1,000 mg for 3 years while the control group (n=?306) received neither supplementation nor placebo. Daily vitamin D and calcium supplementation have a positive effect on the skeleton in ambulatory postmenopausal women. INTRODUCTION: vitamin D deficiency is common in the elderly, and vitamin D levels are associated with low bone mineral density (BMD). The working hypothesis was that vitamin D and calcium supplementation could prevent bone loss in ambulatory postmenopausal women. METHODS: the OSTPRE-FPS was a randomized population-based open trial with a 3-year follow-up in 3,432 women (aged 66 to 71 years). A randomly selected subsample of 593 subjects underwent BMD measurements. The supplementation group (n=?287) received daily cholecalciferol 800 IU + calcium 1,000 mg for 3 years while the control group (n=?306) received neither supplementation nor placebo. RESULTS: in the intention-to-treat analysis, total body BMD (n=?362) increased significantly more in the intervention group than in the control group (0.84% vs. 0.19%, p=?0.011). The BMD change differences at the lumbar spine (p=?0.372), femoral neck (p=?0.188), trochanter (p=?0.085), and total proximal femur (p=?0.070) were statistically nonsignificant. Analyses in compliant women (? 80% of use) resulted in stronger and statistically significant effects at the total body and femoral regions. CONCLUSION: daily vitamin D and calcium supplementation have a positive effect on the skeleton in ambulatory postmenopausal women with adequate nutritional calcium intake.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/524/CN-00781524/frame.html>

Record #219 of 370



ID: CN-00751780

AU: Small DS

AU: Payne CD

AU: Kothare P

AU: Yuen E

AU: Natanegara F

AU: Teng Loh M

AU: Jakubowski JA

AU: Richard Lachno D

AU: Li YG

AU: Winters KJ

AU: Farid NA

AU: Ni L

AU: Salazar DE

AU: Tomlin M

AU: Kelly R

TI: Pharmacodynamics and pharmacokinetics of single doses of prasugrel 30 mg and clopidogrel 300 mg in healthy Chinese and white volunteers: an open-label trial.

SO: Clinical therapeutics

YR: 2010

VL: 32

NO: 2

PG: 365-79

PM: PUBMED 20206794

PT: Comparative Study; Journal Article; Randomized Controlled Trial

KY: Administration, Oral;Asian Continental Ancestry Group;Blood Platelets [drug effects] [metabolism];Cell Adhesion Molecules [blood];China [ethnology];European Continental Ancestry Group;Flow Cytometry;Microfilament Proteins [blood];Phosphoproteins [blood];Piperazines [administration & dosage] [adverse effects] [pharmacokinetics];Platelet Aggregation [drug effects];Platelet Aggregation Inhibitors [administration & dosage] [adverse effects] [pharmacokinetics];Platelet Function Tests;Purinergic P2 Receptor Antagonists;Receptors, Purinergic P2 [blood];Receptors, Purinergic P2Y12;Singapore [epidemiology];Thiophenes [administration & dosage] [adverse effects]

[pharmacokinetics];Ticlopidine [administration & dosage] [adverse effects] [analogs & derivatives]
[pharmacokinetics];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

CC: SR-PVD

DOI: 10.1016/j.clinthera.2010.02.015

AB: BACKGROUND: Prasugrel is an oral antiplatelet agent approved for the reduction of atherothrombotic cardiovascular events in patients presenting with acute coronary syndrome and undergoing percutaneous coronary intervention. Although the approved loading dose is 60 mg, earlier studies of prasugrel suggested that active-metabolite exposure and pharmacodynamic response may be higher in Asian subjects than in white subjects. **OBJECTIVES:** This study compared the pharmacodynamic response to a single 30-mg dose of prasugrel in healthy Chinese and white subjects and the response to a single 30-mg dose of prasugrel and a single 300-mg dose of clopidogrel in healthy Chinese subjects. The pharmacokinetics and tolerability of both drugs were also assessed. **METHODS:** This was an open-label, single-dose study conducted in Singapore. Chinese subjects were randomly allocated to receive prasugrel 30 mg or clopidogrel 300 mg; after a 14-day washout period, they received the alternative drug. White subjects received only prasugrel 30 mg. Blood samples for pharmacodynamic assessments were collected before dosing and at 0.5, 1, 2, 4, and 24 hours after dosing. Three methods were used to measure inhibition of platelet aggregation (IPA)-traditional light transmission aggregometry (LTA), the Verify Now P2Y12 (VN-P2Y12) assay, and a vasodilator-stimulated phosphoprotein (VASP) phosphorylation flow cytometry assay-and their results were compared. Blood samples for pharmacokinetic assessments were collected at 0.25, 0.5, 1, 1.5, 2, 4, 8, 12, and 24 hours after dosing. Concentrations of the active metabolite of prasugrel were measured using a validated LC-MS/MS method. **RESULTS:** The study enrolled 18 Chinese subjects and 14 white subjects. Chinese subjects had a mean (SD) age of 31 (10) years and a mean body weight of 65.2 (8.9) kg; 83% were male. The corresponding values for white subjects were 30 (10) years, 77.2 (12.4) kg, and 86%. Thirty of the 32 enrolled subjects completed the study. Two Chinese men were withdrawn from the study, one due to a low platelet-rich plasma count after receipt of prasugrel 30 mg and the other due to mild, intermittent rectal bleeding after bowel movements that began approximately 2 days after receipt of clopidogrel 300 mg. The mean IPA with prasugrel was significantly higher in Chinese than in white subjects at 0.5, 1, and 2 hours after dosing ($P < 0.05$), but not at 4 or 24 hours. In Chinese subjects, mean maximal IPA (87%) occurred 1 hour after prasugrel dosing; in white subjects, mean maximal IPA (78%) occurred 2 hours after prasugrel dosing. In Chinese subjects, the mean IPA was significantly higher at all time points after administration of prasugrel 30 mg than after administration of clopidogrel 300 mg ($P < 0.001$). After administration of Clopidogrel 300 mg in Chinese subjects, mean maximal IPA (58%) occurred at 4 hours. The VN-P2Y12 and VASP phosphorylation assays yielded results comparable to those obtained by LTA. Mean exposure to prasugrel's active metabolite was higher in Chinese than in white subjects (geometric least squares mean ratio for $AUC(0-t) = 1.47$ (90% CI, 1.24-1.73). Both drugs were well tolerated. **CONCLUSIONS:** In this study, platelet inhibition was significantly higher in Chinese than in white subjects up to 2

hours after a single 30-mg dose of prasugrel. Platelet inhibition was significantly higher in Chinese subjects at all time points after a 30-mg dose of prasugrel than after a 300-mg dose of clopidogrel. Both treatments were generally well tolerated.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/780/CN-00751780/frame.html>

Record #220 of 370



ID: CN-00767417

AU: Szmuiłowicz E

AU: el-Jawahri A

AU: Chiappetta L

AU: Kamdar M

AU: Block S

TI: Improving residents' end-of-life communication skills with a short retreat: a randomized controlled trial.

SO: Journal of palliative medicine

YR: 2010

VL: 13

NO: 4

PG: 439-52

PM: PUBMED 20201666

XR: EMBASE 2010257926

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Analysis of Variance; Clinical Competence [standards] [statistics & numerical data]; Communication; Curriculum; Education; Educational Measurement [standards] [statistics & numerical data]; Educational Status; Illinois; Internal Medicine [education] [standards] [statistics & numerical data]; Internship and Residency [standards] [statistics & numerical data]; Massachusetts; Palliative Care [standards]; Physician-Patient Relations; Psychometrics; Questionnaires; Terminal Care [standards]; Truth Disclosure; United States; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Adult; Article; Audio Recording; Clinical Article; Clinical Trial; *Communication Skill; Controlled Clinical

Trial; Controlled Study; Doctor Patient Relation; Emotion; Female; Human; Male; Medical Practice; Questionnaire; Randomized Controlled Trial; Residency Education; *Terminal Care

DOI: 10.1089/jpm.2009.0262

AB: BACKGROUND: Internal medicine residents are largely unprepared to carry out end-of-life (EOL) conversations. There is evidence that these skills can be taught, but data from randomized controlled trials are lacking. PURPOSE: We studied whether a day-long communication skills training retreat would lead to enhanced performance of and confidence with specific EOL conversations. We also studied the effect of the retreat on residents' ability to respond to patient emotions. METHODS: PGY-2 resident volunteers were randomly assigned to a retreat group or a control group. The retreat involved a combination of teaching styles and skills practice with standardized patients. All participants completed questionnaires and were evaluated carrying out two types of conversations (breaking bad news or discussing direction of care) with a standardized patient before (T1) and after (T2) the intervention phase. Conversations were audio-taped and later rated by a researcher blinded to group assignment and time of assessment. RESULTS: Forty-nine residents agreed to randomization (88%) with 23 residents randomized to the retreat group and 26 to the control group. Compared to controls, retreat participants demonstrated higher T2 scores for breaking bad news, discussing direction of care, and responding to emotion. Comparing T2 to T1, the retreat group's improvement in responding to emotion was statistically significant. The retreat group's confidence improved significantly only for the breaking bad news construct. CONCLUSIONS: A short course for residents can significantly improve specific elements of resident EOL conversation performance, including the ability to respond to emotional cues.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/417/CN-00767417/frame.html>

Record #221 of 370



ID: CN-00767419

AU: Salovaara K

AU: Tuppurainen M

AU: Kärkkäinen M

AU: Rikkonen T

AU: Sandini L

AU: Sirola J

AU: Honkanen R

AU: Alhava E

AU: Kröger H

TI: Effect of vitamin D(3) and calcium on fracture risk in 65- to 71-year-old women: a population-based 3-year randomized, controlled trial--the OSTPRE-FPS.

SO: Journal of bone and mineral research

YR: 2010

VL: 25

NO: 7

PG: 1487-95

PM: PUBMED 20200964

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Calcium [administration & dosage] [therapeutic use];Cholecalciferol [administration & dosage] [therapeutic use];Dietary Supplements;Finland [epidemiology];Fractures, Bone [epidemiology] [prevention & control];Osteoporosis, Postmenopausal [complications] [drug therapy];Risk Factors;Aged[checkword];Female[checkword];Humans[checkword]

CC: SR-MUSKEL

DOI: 10.1002/jbmr.48

AB: Antifracture efficacy of high-dose vitamin D (800 IU) and calcium (1000 mg) remains controversial. To determine whether daily 800 IU of vitamin D and 1000 mg of calcium supplementation prevents fractures, we randomized 3432 women of the population-based Osteoporosis Risk Factor and Prevention (OSTPRE) Study cohort (ages 65 to 71 years) living in the region of northern Savonia, Finland (latitude 62 degrees to 64 degrees N) for 3 years to receive 800 IU of cholecalciferol and 1000 mg of calcium as calcium carbonate or to a control group that did not receive placebo. The main outcome measure was incident fractures. Fracture data were collected in telephone interviews and validated. Data on 3195 women, 1586 in the intervention group and 1609 in the control group, were available for analysis. In adjusted Cox proportional hazards models, the risk of any fracture decreased in the vitamin D and calcium group by 17% [adjusted hazard ratio (aHR) = 0.83; 95% confidence interval (CI) 0.61-1.12], and the risk of any nonvertebral fracture decreased by 13% (aHR = 0.87; 95% CI 0.63-1.19). The risk of distal forearm fractures decreased by 30% (aHR = 0.70; 95% CI 0.41-1.20), and the risk of any upper extremity fractures decreased by 25% (aHR = 0.75; 95% CI 0.49-1.16), whereas the risk of lower extremity fractures remained essentially equal (aHR = 1.02; 95% CI 0.58-1.80). None of these effects reached statistical significance. In conclusion, this study did not produce statistically significant evidence that vitamin D and calcium supplementation prevents fractures in a 65- to 71-year-old general population of postmenopausal women.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/419/CN-00767419/frame.html>

Record #222 of 370



ID: CN-00750775

AU: Onishi T

AU: Shimada K

AU: Sato H

AU: Seki E

AU: Watanabe Y

AU: Sunayama S

AU: Ohmura H

AU: Masaki Y

AU: Nishitani M

AU: Fukao K

AU: Kume A

AU: Sumide T

AU: Mokuno H

AU: Naito H

AU: Kawai S

AU: Daida H

TI: Effects of phase III cardiac rehabilitation on mortality and cardiovascular events in elderly patients with stable coronary artery disease.

SO: Circulation journal

YR: 2010

VL: 74

NO: 4

PG: 709-14

PM: PUBMED 20208382

PT: Clinical Trial, Phase III; Controlled Clinical Trial; Journal Article; Research Support, Non-U.S. Gov't

KY: Acute Coronary Syndrome [epidemiology] [mortality]; Blood Glucose [metabolism]; Body Mass Index; Coronary Artery Disease [blood] [rehabilitation]; Diet; Exercise Therapy; Follow-Up Studies; Heart Failure [epidemiology] [mortality]; Incidence; Japan; Lipids [blood]; Patient Education as Topic; Proportional Hazards Models; Stroke [epidemiology] [mortality]; Treatment Outcome; Aged[checkword]; Humans[checkword]; Male[checkword]

CC: SR-ENDOC

AB: BACKGROUND: Cardiac rehabilitation (CR) has numerous benefits, including reduction of mortality and cardiovascular events, in patients with coronary artery disease (CAD). However, the long-term effect of phase III CR in elderly patients with stable CAD is still unknown.

METHODS AND RESULTS: The 111 elderly male CAD patients (≥ 65 years), including 37 subjects participating in supervised CR for 6 months and 74 age-matched controls, were analyzed. The patients were followed for up to 3,500 days, until the occurrence of death or 1 of the following major adverse cardiovascular events (MACE): cardiovascular death, acute coronary syndrome, refractory angina requiring revascularization, admission for congestive heart failure, or stroke. All-cause mortality tended to be lower in the CR group than in the Control group (14% vs 28%, $P=0.081$). The MACE incidence was significantly lower in the CR group than in the Control group (30% vs 62%, $P=0.001$). Multivariate Cox proportional hazard analysis showed that the MACE incidence was significantly lower in the CR group than in the Control group [adjusted hazard ratio 0.43 (95% confidence interval 0.20-0.91), $P=0.027$].

CONCLUSIONS: Phase III CR has the beneficial effect of reducing cardiovascular events even in elderly patients with stable CAD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/775/CN-00750775/frame.html>

Record #223 of 370



ID: CN-00729685

AU: Hirohata A

AU: Yamamoto K

AU: Miyoshi T

AU: Hatanaka K

AU: Hirohata S

AU: Yamawaki H

AU: Komatsubara I

AU: Murakami M

AU: Hirose E

AU: Sato S

AU: Ohkawa K

AU: Ishizawa M

AU: Yamaji H

AU: Kawamura H

AU: Kusachi S

AU: Murakami T

AU: Hina K

AU: Ohe T

TI: Impact of olmesartan on progression of coronary atherosclerosis a serial volumetric intravascular ultrasound analysis from the OLIVUS (impact of OLmesarten on progression of coronary atherosclerosis: evaluation by intravascular ultrasound) trial.

SO: Journal of the American College of Cardiology

YR: 2010

VL: 55

NO: 10

PG: 976-82

PM: PUBMED 20202514

PT: Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Angina Pectoris [drug therapy] [mortality] [ultrasonography];Angioplasty, Balloon, Coronary;Angiotensin II Type 1 Receptor Blockers [adverse effects] [therapeutic use];Blood Pressure [drug effects];Coronary Angiography;Coronary Artery Disease [drug therapy] [ultrasonography];Coronary Vessels [drug effects] [ultrasonography];Disease Progression;Follow-Up Studies;Image Processing, Computer-Assisted [methods];Imidazoles [adverse effects] [therapeutic use];Myocardial Infarction [drug therapy] [ultrasonography];Prospective Studies;Survival Rate;Tetrazoles [adverse effects] [therapeutic

use];Ultrasonography, Interventional
[methods];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-HTN: SR-VASC

DOI: 10.1016/j.jacc.2009.09.062

AB: OBJECTIVES: The aim of this study was to evaluate the impact of olmesartan on progression of coronary atherosclerosis. BACKGROUND: Prior intravascular ultrasound (IVUS) trial results suggest slowing of coronary atheroma progression with some medicines but have not shown convincing evidence of regression with angiotension-II receptor blocking agents. METHODS: A prospective, randomized, multicenter trial-OLIVUS (Impact of OLmesartan on progression of coronary atherosclerosis: evaluation by IntraVascular UltraSound)-was performed in 247 stable angina pectoris patients with native coronary artery disease. When these patients underwent percutaneous coronary intervention for culprit lesions, IVUS was performed in their nonculprit vessels (without angiographically documented coronary stenosis [$<50\%$]). Patients were randomly assigned to receive 10 to 40 mg of olmesartan or control and treated with a combination of beta-blockers, calcium channel blockers, diuretics, nitrates, glycemic control agents, and/or statins per physician's guidance. Serial IVUS examinations (baseline and 14-month follow-up) were performed to assess coronary atheroma volume. Volumetric IVUS analyses included lumen, plaque, vessel volume, percent atheroma volume (PAV), percent change in total atheroma volume (TAV) and PAV. RESULTS: Patient characteristics and blood pressure control were identical between the 2 groups. However, follow-up IVUS showed significantly decreased TAV and percent change in PAV in the olmesartan group (5.4% vs. 0.6 % for TAV and 3.1% vs. -0.7% for percent change in PAV, control vs. olmesartan, $p < 0.05$ for all). CONCLUSIONS: These observations suggest a positive role in a potentially lower rate of coronary atheroma progression through the administration of olmesartan, an angiotension-II receptor blocking agent, for patients with stable angina pectoris.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/685/CN-00729685/frame.html>

Record #224 of 370



ID: CN-00751987

AU: Hopkins MH

AU: Fedirko V

AU: Jones DP

AU: Terry PD

AU: Bostick RM

TI: Antioxidant micronutrients and biomarkers of oxidative stress and inflammation in colorectal adenoma patients: results from a randomized, controlled clinical trial.

SO: Cancer epidemiology, biomarkers & prevention

YR: 2010

VL: 19

NO: 3

PG: 850-8

PM: PUBMED 20200432

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adenoma [drug therapy] [metabolism];Antioxidants [therapeutic use];Ascorbic Acid [administration & dosage];Chromatography, High Pressure Liquid;Colorectal Neoplasms [drug therapy] [metabolism];Cystine [blood];Double-Blind Method;Enzyme-Linked Immunosorbent Assay;F2-Isoprostanes [blood];Interleukin-6 [blood];Manganese [administration & dosage];Micronutrients [therapeutic use];Niacin [administration & dosage];Oxidative Stress [drug effects];Pilot Projects;Riboflavin [administration & dosage];Selenomethionine [administration & dosage];Tumor Markers, Biological [analysis];Tumor Necrosis Factor-alpha [blood];Vitamin E [administration & dosage];Zinc [administration & dosage];beta Carotene [administration & dosage];Adult[checkword];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-COLOCA

DOI: 10.1158/1055-9965.EPI-09-1052

AB: Previous epidemiologic observational and experimental studies investigated the potential of antioxidant micronutrients to modulate cancer risk, but these studies produced inconsistent results. In this pilot, randomized, double-blind, placebo-controlled clinical trial (n = 47), we assessed the effects of an antioxidant micronutrient combination (800 mg dl-alpha-tocopherol acetate, 24 mg beta-carotene, 1.0 g vitamin C, 200 microg l-selenomethionine, 7.2 mg riboflavin, 80 mg niacin, 60 mg zinc, 5 mg manganese) given daily over 4 months on oxidative and inflammatory biomarkers in patients with a history of sporadic colorectal adenoma. Plasma tumor necrosis factor-alpha (TNF-alpha), interleukin-6, and F2-isoprostane concentrations were measured using ELISAs, and cystine (CySS) was measured using high-performance liquid chromatography. Plasma TNF-alpha concentration decreased in the active treatment group by 37% relative to the placebo group (P = 0.002), and CySS decreased by 19% (P = 0.03); however, interleukin-6 and F2-isoprostane concentrations decreased in antioxidant-treated nonsmokers but increased in smokers, although these findings were not statistically significant. The decreases of TNF-alpha and CySS were more pronounced in nonsmokers. These

data suggest that (a) an antioxidant micronutrient cocktail can modulate biomarkers of oxidative stress and inflammation in humans and (b) the effects of antioxidant micronutrient supplementation on biomarkers of inflammation and oxidative stress may differ according to smoking status.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/987/CN-00751987/frame.html>

Record #225 of 370

ID: CN-00892335



AU: Karimian F

AU: Darbanian K

AU: Aminian A

AU: Mirsharifi R

AU: Mehrkhani F

AU: Gharaee F

TI: Low rectal anastomosis leakage, keep it or move it.

SO: Biomedical research (Tokyo, Japan)

YR: 2010

VL: 21

NO: 4

PG: 383-8

XR: EMBASE 2011441696

PT: Journal: Article

KY: abdominal drainage // adult // *anastomosis leakage/co [Complication] // article // clinical article // clinical protocol // controlled clinical trial // controlled study // digital rectal examination // female // human // infection control // male // mortality // outcome assessment // peritoneum lavage // *rectum anastomosis // rectum cancer/su [Surgery] // salvage therapy // sepsis // surgical approach // surgical risk // symptomatology // treatment indication // ulcerative colitis/su [Surgery]

AB: Leakage of low rectal anastomosis is a potentially life threatening complication. Conventionally, in those patients who can tolerate a major operation, resection of anastomosis with end stoma is attempted. This management leads to permanent stoma in many patients. We try to show that in a defined group of patients, with overtly symptomatic clinical leak mandating surgical intervention, the primary anastomosis may be saved. One hundred and fifty seven patients who underwent low rectal anastomosis during 7 years were followed post-operatively for leak. Patients with low rectal anastomosis disruption of less than a quarter of circumference, estimated by digital rectal examination, were selected. Proximal loop diversion with complete on-table wash out of distal limb and temporary closure of efferent opening plus peritoneal irrigation and drainage was performed as salvage procedure. Fifteen patients (9.5%) with major leakage and small anastomotic disruption, 10 males (66.6%) and 5 females (33.3%) were enrolled. The indication of primary operation was low rectal cancer in 12 (80%) patients and ulcerative colitis in 3 (20%) patients. Management was successful in 12 (80%) patients leading to preservation of their low rectal anastomosis and control of sepsis. Salvage procedure failed in three (20%) patients leaving no option but discontinuing the pelvic anastomosis in favor of end colostomy. There was one in-hospital death (6.66%). Patients with small disruption at low rectal anastomosis may be managed without resection of primary anastomosis. Controlling peritoneal infection and inhibiting ongoing contamination by proximal diverting stoma will help small deep pelvic leaks heal.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/335/CN-00892335/frame.html>

Record #226 of 370



ID: CN-00900970

AU: Al-Jurayyan NAM

AU: Al-Jurayyan RNA

AU: Al Senani AMS

TI: Efficacy of a high initial dose of L-thyroxine in the treatment of congenital hypothyroidism.

SO: Current Pediatric Research

YR: 2010

VL: 14

NO: 2

PG: 125-30

XR: EMBASE 2012148043

PT: Journal: Article

KY: article // clinical article // *congenital hypothyroidism/cn [Congenital Disorder] // *congenital hypothyroidism/di [Diagnosis] // *congenital hypothyroidism/dt [Drug Therapy] // *congenital hypothyroidism/et [Etiology] // controlled clinical trial // controlled study // drug dose reduction // drug efficacy // drug monitoring // drug response // free thyroxine index // human // hyperthyroxinemia // infant // longitudinal study // newborn // newborn screening // outcome assessment // patient monitoring // prospective study // recommended drug dose // Saudi Arabia // thyroid function test // thyrotropin blood level // *levothyroxine/ct [Clinical Trial] // *levothyroxine/dt [Drug Therapy] // thyrotropin // thyroxine/ec [Endogenous Compound]

AB: Results of a treatment strategy using an initial dosage of 10 - 15 mug/kg/day of L-thyroxine was evaluated in a prospective longitudinal study in King Khalid University Hospital, Riyadh, Saudi Arabia. Thyroid-stimulating hormone (TSH) and free-thyroxine (FT₄) measurements being taken at 3 weeks, 6 weeks, 3 months, 6 months, 9 months and one year of the start of therapy. Forty-two newborns with confirmed primary congenital hypothyroidism (CH), detected by neonatal screening, were treated with the same therapeutic strategy (10 - 15 mug per kg per day). Twenty-one (50%) ectopic, 13 (31%) athyreotic, and 8 (19%) eutopic with increased uptake. A mean L-thyroxine dosage of 11.3 mug per kg per day (range 9.7 - 14.7) at the onset of treatment, normalized the FT₄ (9-30 Pmol/L) levels at three weeks in 100%, and TSH (<10 mU/L) levels at six weeks in 90.5% of cases. However, hyperthyroxinaemia, FT₄ levels ranging from 38 to 55 Pmol/L, was observed in six (14.3%) patients of different aetiology, which required modification in the doses given. They were initially started on higher dosages (12.3 - 14.7 mug per kg per day). Although an empirical initial dosage of 10 - 15 mug per kg per day of L-thyroxine is adequate and rapid in normalizing the thyroid status of infants with congenital hypothyroidism detected by neonatal screening, many infants who were started on higher dosages (12.3 - 14.7) showed elevated levels of FT₄ which could expose infants to a dangerous hyperthyroidism, therefore, an initial lower dosage of 10 - 12 mug per kg per day of L-thyroxine with frequent and close monitoring of doses, and FT₄, and TSH levels is more appropriate and safer than the currently recommended dosage of 10 -15 mug per kg per day for the initial treatment of infants with congenital hypothyroidism.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/970/CN-00900970/frame.html>

Record #227 of 370



ID: CN-00908509

AU: Jidy MD

AU: Rodriguez AP

AU: Llanes RF

AU: Farinas LB

AU: Sanchez HG

AU: Fernandez RV

AU: Imia LG

AU: Calzada RF

AU: Hernandez JM

TI: Challenge clinical trial for evaluation of a vaccine. [Spanish]

SO: Revista cubana de medicina tropical

YR: 2010

VL: 62

NO: 3

PG: 194-9

PM: PUBMED 23437548

XR: EMBASE 23437548

PT: Journal: Article

KY: article // *cholera/pc [Prevention] // controlled clinical trial // controlled study // double blind procedure // human // immunology // randomized controlled trial // *Vibrio cholerae // *cholera vaccine

AB: INTRODUCTION: live attenuated oral *Vibrio cholerae* O1 El Tor, Ogawa strain 638 has demonstrated to be well tolerated and immunogenic when administered orally in studies carried out in healthy volunteers. OBJECTIVES: to evaluate the protection against cholera infection in a challenge clinical trial, for the technological and pharmaceutical scale-up of this vaccinal candidate as active ingredient at industrial level. METHODS: a total of 21 healthy volunteers were involved in this trial; the vaccine candidate was administered to 12 of them and the remaining nine were given the placebo. Twenty eight days later, all of them received an infective dose of a *V. cholerae* virulent strain. RESULTS: diarrheas were observed in 7 out of 9 placebos whereas not a single vaccinated volunteer showed diarrheas. More frequent and intense loose stools were found in the placebo volunteers with O-blood group. All volunteers in the placebo group excreted *V. cholerae*, but only three (25%) out of the 12 vaccinated volunteers did so. CONCLUSION: in this challenge clinical trial model, the 638 strain proved to protect people against the diarrhea caused by a virulent *V. cholerae* strain.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/509/CN-00908509/frame.html>

Record #228 of 370



ID: CN-00897762

AU: Khan AQ

AU: Kumar KK

AU: Sherwani MKA

AU: Jameel SN

TI: Epidural injections for lumbosciatica syndrome-medications and routes.

SO: Journal of Clinical Orthopaedics and Trauma

YR: 2010

VL: 1

NO: 2

PG: 95-8

XR: EMBASE 2012064663

PT: Journal: Article


KY: adult // application site pain/si [Side Effect] // article // bed rest // clinical feature // comparative effectiveness // controlled study // disease association // drug efficacy // drug safety // drug tolerability // female // follow up // hiccup/si [Side Effect] // human // hypotension/si [Side Effect] // infection/si [Side Effect] // intermethod comparison // limb weakness/si [Side Effect] // low back pain/si [Side Effect] // *lumbar disk hernia/dt [Drug Therapy] // *lumbar disk hernia/th [Therapy] // major clinical study // male // nausea/si [Side Effect] // pain assessment // postdural puncture headache/si [Side Effect] // priority journal // randomized controlled trial // syncope/si [Side Effect] // traction therapy // transcutaneous nerve stimulation // vascular disease/si [Side Effect] // *methylprednisolone/ae [Adverse Drug Reaction] // *methylprednisolone/ct [Clinical Trial] // *methylprednisolone/ad [Drug Administration] // *methylprednisolone/cm [Drug Comparison] // *methylprednisolone/dt [Drug Therapy] // *methylprednisolone/ei [Epidural Drug Administration] // *methylprednisolone/sp [Intraspinal Drug Administration] // *triamcinolone/ae [Adverse Drug Reaction] // *triamcinolone/ct [Clinical Trial] // *triamcinolone/ad [Drug Administration] // *triamcinolone/cm [Drug Comparison] // *triamcinolone/dt [Drug Therapy] //

*triamcinolone/ei [Epidural Drug Administration] // *triamcinolone/sp [Intraspinal Drug Administration]

DOI: 10.1016/S0976-5662%2811%2960020-9

AB: It was a prospective study involving 103 patients, suffering from lumbosciatic syndrome due to various causes. Purpose of this study was to study the efficacy of two steroids methylprednisolone and triamcinolone used epidurally via lumbar and caudal route and to highlight value of this simple procedure in lumbosciatic syndrome. About 80% people suffer from back pain at some point of life. Majority of the patients can be managed effectively with conservative treatment like bed rest, analgesics, lumbar traction and transcutaneous electrical nerve stimulation (TENS), etc. The epidural steroid injection has an important role in the patients of lumbosciatic syndrome due to various causes. Its judicious use can avoid the surgery in many patients. Between September 2003 and August 2004, 103 patients received 309 injections (156 lumbar route and 153 caudal). Pain was assessed by visual analog scale, SLR, and Lasegue test. Three epidural injections were given at a monthly interval and patients followed up for minimum period of 4 months. Patients were randomly divided into 2 groups, on the basis of whether they received methylprednisolone or triamcinolone and further into 2 subgroups for either lumbar/caudal route. 78.43% in caudal group and 82.6% had excellent to good results. Complications were minimal and that too in the lumbar route only. Data was analyzed using t-test. Significant difference ($p < 0.01$) was seen in improvement of low backache (LBA) by both routes and both drugs but the difference was statistically insignificant ($p > 0.05$) among 2 steroid groups and 2 routes. Epidural steroid injection (triamcinolone/methylprednisolone) through either caudal or lumbar route is an excellent conservative method for treatment of LBA with sciatica. Caudal route is relatively safer than lumbar, so lumbar route should be used by experienced persons and in setups where resuscitation equipments are available. 2010 Delhi Orthopedic Association.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/762/CN-00897762/frame.html>

Record #229 of 370 

ID: CN-00803348

AU: Ferrari J

TI: Randomized controlled trial of atorvastatin in mild to moderate Alzheimer disease: LEADe. [German]

SO: Journal fur Neurologie, Neurochirurgie und Psychiatrie

YR: 2010

VL: 11

NO: 4

PG: 85

XR: EMBASE 2010652270

PT: Journal: Note

KY: adult // aged // *Alzheimer disease // clinical trial // cognition // controlled clinical trial // controlled study // double blind procedure // drug efficacy // drug safety // human // major clinical study // Mini Mental State Examination // note // randomized controlled trial // scoring system // screening // *atorvastatin/ct [Clinical Trial] // donepezil // low density lipoprotein cholesterol/ec [Endogenous Compound]

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/348/CN-00803348/frame.html>

Record #230 of 370



ID: CN-00714185

AU: Anon

TI: [Public title] Study in elderly Alzheimer's subjects on an established and well tolerated dose of Aricept to assess skin tolerability, skin irritation and adhesion with three consecutive seven-day applications of the 350 mg donepezil transdermal patch-system; [Scientific title] A randomized, placebo-controlled study in elderly Alzheimer's subjects on an established and well tolerated dose of Aricept to assess skin tolerability, skin irritation and adhesion with three consecutive seven-day applications of the 350 mg donepezil transdermal patch-system

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/185/CN-00714185/frame.html>

Record #231 of 370



ID: CN-00722526

AU: Chuah LY

AU: Chong DL

AU: Chen AK

AU: Rekshan WR

AU: Tan JC

AU: Zheng H

AU: Chee MW

TI: Donepezil improves episodic memory in young individuals vulnerable to the effects of sleep deprivation.

SO: Sleep

YR: 2009

VL: 32

NO: 8

PG: 999-1010

PM: PUBMED 19725251

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Administration, Oral;Arousal [drug effects];Brain [drug effects];Brain Mapping;Cholinesterase Inhibitors [pharmacology];Cross-Over Studies;Dominance, Cerebral [drug effects];Double-Blind Method;Drug Administration Schedule;Indans [pharmacology];Magnetic Resonance Imaging;Mental Recall [drug effects];Nootropic Agents [pharmacology];Piperidines [pharmacology];Premedication;Recognition (Psychology) [drug effects];Sleep Deprivation [drug therapy] [psychology];Verbal Learning [drug effects];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

CC: SR-DEMENTIA

AB: **STUDY OBJECTIVES:** We investigated if donepezil, a long-acting orally administered cholinesterase inhibitor, would reduce episodic memory deficits associated with 24 h of sleep deprivation. **DESIGN:** Double-blind, placebo-controlled, crossover study involving 7 laboratory visits over 2 months. Participants underwent 4 functional MRI scans; 2 sessions (donepezil or placebo) followed a normal night's sleep, and 2 sessions followed a night of sleep deprivation. **SETTING:** The study took place in a research laboratory. **PARTICIPANTS:** 26 young, healthy volunteers with no history of any sleep, psychiatric, or neurologic disorders. **INTERVENTIONS:** 5 mg of donepezil was taken once daily for approximately 17 days. **MEASUREMENTS AND RESULTS:** Subjects were scanned while performing a semantic judgment task and tested for word recognition outside the scanner 45 minutes later. Sleep deprivation increased the frequency of non-responses at encoding and impaired delayed recognition. No benefit of

donepezil was evident when participants were well rested. When sleep deprived, individuals who showed greater performance decline improved with donepezil, whereas more resistant individuals did not benefit. Accompanying these behavioral effects, there was corresponding modulation of task-related activation in functionally relevant brain regions. Brain regions identified in relation to donepezil-induced alteration in non-response rates could be distinguished from regions relating to improved recognition memory. This suggests that donepezil can improve delayed recognition in sleep-deprived persons by improving attention as well as enhancing memory encoding. CONCLUSIONS: Donepezil reduced decline in recognition performance in individuals vulnerable to the effects of sleep deprivation. Additionally, our findings demonstrate the utility of combined fMRI-behavior evaluation in psychopharmacological studies.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/526/CN-00722526/frame.html>

Record #232 of 370



ID: CN-00719780

AU: Kishnani PS

AU: Sommer BR

AU: Handen BL

AU: Seltzer B

AU: Capone GT

AU: Spiridigliozzi GA

AU: Heller JH

AU: Richardson S

AU: McRae T

TI: The efficacy, safety, and tolerability of donepezil for the treatment of young adults with Down syndrome.

SO: American journal of medical genetics. Part A

YR: 2009

VL: 149A

NO: 8

PG: 1641-54

PM: PUBMED 19606472


PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Demography; Double-Blind Method; Down Syndrome [drug therapy]; Indans [adverse effects] [pharmacology] [therapeutic use]; Learning [drug effects]; Nootropic Agents [adverse effects] [pharmacology] [therapeutic use]; Piperidines [adverse effects] [pharmacology] [therapeutic use]; Treatment Outcome; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Young Adult[checkword]

DOI: 10.1002/ajmg.a.32953

AB: The objective of our study was to assess the efficacy and safety of donepezil in young adults with Down syndrome (DS) but no evidence of Alzheimer disease (AD). A 12-week, randomized, double-blind, placebo-controlled study with a 12-week, open-label extension was conducted. The intervention consisted of donepezil (5-10 mg/day) in young adults (aged 18-35 years) with DS, but no AD. The primary measure was the Severe Impairment Battery (SIB) test and secondary measures were the Vineland Adaptive Behavior Scales (VABS), the Rivermead Behavioral Memory Test for Children, and the Clinical Evaluation of Language Fundamentals, Third Edition. At baseline, 123 subjects were randomly assigned treatment with donepezil or placebo. During the double-blind phase, SIB scores improved significantly from baseline in both groups, with no significant between-group differences. During the open-label phase, SIB scores in the original donepezil group remained stable; the original placebo group showed an improvement similar to that seen in the double-blind phase. VABS scores improved for donepezil, but not placebo, during the double-blind phase (observed cases, $P = 0.03$; last observation carried forward, $P = 0.07$). Post hoc responder analyses were significant for donepezil using three of five response definitions ($P < \text{or} = 0.045$). Adverse event rates were comparable to AD studies. In this first large-scale, multicenter trial of a pharmacological agent for DS, donepezil appears safe. Efficacy interpretation was limited for the primary measure due to apparent learning/practice and ceiling effects. Outcomes in post hoc analyses suggested efficacy in some, but not all subjects, consistent with phenotypic variability of DS. Additional studies are required to confirm potential benefits of donepezil in this population.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/780/CN-00719780/frame.html>

Record #233 of 370 

ID: CN-00702583

AU: Doody RS

AU: Ferris SH

AU: Salloway S

AU: Sun Y

AU: Goldman R

AU: Watkins WE

AU: Xu Y

AU: Murthy AK

TI: Donepezil treatment of patients with MCI: a 48-week randomized, placebo-controlled trial.

SO: Neurology

YR: 2009

VL: 72

NO: 18

PG: 1555-61

PM: PUBMED 19176895

XR: EMBASE 2009586688

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [physiopathology] [prevention & control];Cholinesterase Inhibitors [administration & dosage] [adverse effects];Cognition Disorders [drug therapy] [physiopathology] [psychology];Disease Progression;Double-Blind Method;Endpoint Determination [methods];Indans [administration & dosage] [adverse effects];Neuropsychological Tests;Outcome Assessment (Health Care) [methods];Patient Compliance [statistics & numerical data];Piperidines [administration & dosage] [adverse effects];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1212/01.wnl.0000344650.95823.03

AB: BACKGROUND: Treatment of mild cognitive impairment (MCI) with cholinesterase inhibitors may improve symptoms. METHODS: In this multicenter, randomized, placebo-controlled trial, subjects with MCI entered a 3-week placebo run-in period followed by 48 weeks of double-blind donepezil (5 mg/day for 6 weeks, then 10 mg/day for 42 weeks) or placebo treatment. Primary efficacy variables included change from baseline in the modified

Alzheimer Disease Assessment Scale-cognitive subscale (ADAS-Cog) and Clinical Dementia Rating Scale-sum of boxes (CDR-SB) after 48 weeks of treatment (modified intention-to-treat analysis). Secondary efficacy measures evaluated cognition, behavior, and function. RESULTS: The dual primary efficacy endpoint was not reached. We noted a small, but significant, decrease in modified ADAS-Cog scores in favor of donepezil at study endpoint. Little change from baseline in CDR-SB and secondary variables was observed for either group. Patient Global Assessment scores favored donepezil at all time points except week 12 ($p < \text{or} = 0.05$). Perceived Deficits Questionnaire scores favored donepezil at week 24 ($p = 0.05$). Clinical Global Impression of Change-MCI scores favored donepezil only at week 6 ($p = 0.04$). Adverse events were generally mild or moderate. More donepezil-treated subjects (18.4%) discontinued treatment due to adverse events than placebo-treated subjects (8.3%). CONCLUSIONS: Donepezil demonstrated small but significant improvement on the primary measure of cognition but there was no change on the primary measure of global function. Most other measures of global impairment, cognition, and function were not improved, possibly because these measures are insensitive to change in MCI. Responses on subjective measures suggest subjects perceived benefits with donepezil treatment.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/583/CN-00702583/frame.html>

Record #234 of 370



ID: CN-00730823

AU: Wilkinson D

AU: Schindler R

AU: Schwam E

AU: Waldemar G

AU: Jones RW

AU: Gauthier S

AU: Lopez OL

AU: Cummings J

AU: Xu Y

AU: Feldman HH

TI: Effectiveness of donepezil in reducing clinical worsening in patients with mild-to-moderate alzheimer's disease.

SO: Dementia and geriatric cognitive disorders

YR: 2009

VL: 28

NO: 3

PG: 244-51

PM: PUBMED 19786776

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [psychology];Disease Progression;Double-Blind Method;Indans [therapeutic use];Neuropsychological Tests;Nootropic Agents [therapeutic use];Odds Ratio;Piperidines [therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1159/000241877

AB: BACKGROUND: Therapeutic endpoints based on reduced clinical worsening represent clinically relevant and realistic goals for patients suffering from progressive neurodegenerative disorders such as Alzheimer's disease (AD). METHODS: Data from 906 patients (388 receiving placebo; 518 receiving donepezil) with mild-to-moderate AD [Mini-Mental State Examination (MMSE) score 10-27] were pooled from 3 randomized, double-blind placebo-controlled studies. Clinical worsening was defined as decline in (1) cognition (MMSE), (2) cognition and global ratings (Clinician's Interview-Based Impression of Change plus Caregiver Input/Gottfries-Br ne-Steen scale) or (3) cognition, global ratings and function (various functional measures). RESULTS: At week 24, lower percentages of donepezil-treated patients than placebo patients met the criteria for clinical worsening, regardless of the definition. The odds of declining were significantly reduced for donepezil-treated versus placebo patients ($p < 0.0001$; all definitions). Among patients meeting criteria for clinical worsening, mean declines in MMSE scores were greater for placebo than donepezil-treated patients. CONCLUSION: In this population, donepezil treatment was associated with reduced odds of clinical worsening of AD symptoms. Moreover, patients worsening on donepezil were likely to experience less cognitive decline than expected if left untreated. This suggests that AD patients showing clinical worsening on donepezil may still derive benefits compared with placebo/untreated patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/823/CN-00730823/frame.html>

Record #235 of 370



ID: CN-00714171

AU: Anon


TI: Preliminary efficacy and safety study of ST101 plus aricept in Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/171/CN-00714171/frame.html>

Record #236 of 370 

ID: CN-00724773

AU: Anon


TI: A Pfizer Inc. and Eisai Inc. sponsored randomized, double-blind, placebo-controlled, multicountry study of two treatment strategies for patients with mild to moderate Alzheimer's disease who do not show clinical improvement after 12 to 24 weeks of Aricept treatment

SO: Esai [www.clinicalstudyresults.org]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/773/CN-00724773/frame.html>

Record #237 of 370 

ID: CN-00720710

AU: Jones R

AU: Sheehan B

AU: Phillips P

AU: Juszczak E

AU: Adams J

AU: Baldwin A
AU: Ballard C
AU: Banerjee S
AU: Barber B
AU: Bentham P
AU: Brown R
AU: Burns A
AU: Dening T
AU: Findlay D
AU: Gray R
AU: Griffin M
AU: Holmes C
AU: Hughes A
AU: Jacoby R
AU: Johnson T
AU: Jones R
AU: Knapp M
AU: Lindesay J
AU: McKeith I
AU: McShane R
AU: Macharouthu A
AU: O'Brien J
AU: Onions C
AU: Passmore P
AU: Raftery J
AU: Ritchie C
AU: Howard R

TI: DOMINO-AD protocol: donepezil and memantine in moderate to severe Alzheimer's disease
- a multicentre RCT.

SO: Trials

YR: 2009

VL: 10

PG: 57

PM: PUBMED 19630974

XR: EMBASE 2009432211

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Dopamine Agents [therapeutic use];Evidence-Based Medicine;Indans [therapeutic use];Memantine [therapeutic use];Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Research Design;Severity of Illness Index;Humans[checkword]

CC: SR-DEMENTIA

DOI: 10.1186/1745-6215-10-57

AB: BACKGROUND: Alzheimer's disease (AD) is the commonest cause of dementia. Cholinesterase inhibitors, such as donepezil, are the drug class with the best evidence of efficacy, licensed for mild to moderate AD, while the glutamate antagonist memantine has been widely prescribed, often in the later stages of AD. Memantine is licensed for moderate to severe dementia in AD but is not recommended by the England and Wales National Institute for Health and Clinical Excellence. However, there is little evidence to guide clinicians as to what to prescribe as AD advances; in particular, what to do as the condition progresses from moderate to severe. Options include continuing cholinesterase inhibitors irrespective of decline, adding memantine to cholinesterase inhibitors, or prescribing memantine instead of cholinesterase inhibitors. The aim of this trial is to establish the most effective drug option for people with AD who are progressing from moderate to severe dementia despite treatment with donepezil. METHOD: DOMINO-AD is a pragmatic, 15 centre, double-blind, randomized, placebo controlled trial. Patients with AD, currently living at home, receiving donepezil 10 mg daily, and with Standardized Mini-Mental State Examination (SMMSE) scores between 5 and 13 are being recruited. Each is randomized to one of four treatment options: continuation of donepezil with memantine placebo added; switch to memantine with donepezil placebo added; donepezil and memantine together; or donepezil placebo with memantine placebo. 800 participants are being recruited and treatment continues for one year. Primary outcome measures are cognition (SMMSE) and activities of daily living (Bristol Activities of Daily Living Scale). Secondary outcomes are non-cognitive dementia symptoms (Neuropsychiatric Inventory), health related quality of life (EQ-5D and DEMQOL-proxy), carer burden (General Health Questionnaire-12), cost effectiveness (using Client Service Receipt Inventory) and

institutionalization. These outcomes are assessed at baseline, 6, 18, 30 and 52 weeks. All participants will be subsequently followed for 3 years by telephone interview to record institutionalization. DISCUSSION: There is considerable debate about the clinical and cost effectiveness of anti-dementia drugs. DOMINO-AD seeks to provide clear evidence on the best treatment strategies for those managing patients at a particularly important clinical transition point. TRIAL REGISTRATION: Current controlled trials ISRCTN49545035.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/710/CN-00720710/frame.html>

Record #238 of 370



ID: CN-00720651

AU: Zaninotto AL

AU: Bueno OF

AU: Pradella-Hallinan M

AU: Tufik S

AU: Rusted J

AU: Stough C

AU: Pompéia S

TI: Acute cognitive effects of donepezil in young, healthy volunteers.

SO: Human psychopharmacology

YR: 2009

VL: 24

NO: 6

PG: 453-64

PM: PUBMED 19637397

PT: Controlled Clinical Trial; Journal Article; Research Support, Non-U.S. Gov't

KY: Affect [drug effects];Cholinesterase Inhibitors [pharmacokinetics]
[pharmacology];Cognition [drug effects];Double-Blind Method;Indans [pharmacokinetics]
[pharmacology];Memory [drug effects];Nootropic Agents [pharmacokinetics]

[pharmacology];Piperidines [pharmacokinetics] [pharmacology];Time Factors;Adult[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

CC: SR-DEMENTIA

DOI: 10.1002/hup.1044


AB: OBJECTIVE: The acute nootropic potential of donepezil in young healthy volunteers has not been adequately investigated mainly because in previous studies: (1) effects were assessed before peak-plasma concentration (Tmax) was reached; (2) only a few cognitive processes were assessed. Here we investigated a myriad of cognitive effects of augmentation of acetylcholine using an acute dose of donepezil in healthy adults at theoretical Tmax.

METHODS: This was a double-blind, placebo controlled, parallel group design study of cognitive effects of acute oral donepezil (5 mg). Subjects were tested twice after donepezil ingestion: 90 min (time that coincides with previous testing in the literature) and 210 min. (theoretical Tmax). The test battery included tasks that tap cognitive domains that are sensitive to acetylcholine manipulations.

RESULTS: At both testing times donepezil improved long-term recall of prose, objects recall, recall of spatial locations, and integration of objects with their locations, some effects having been related to self-reported mood enhancement.

However, improvement of performance in the central executive measure (backward digit span) occurred only at Tmax. CONCLUSION: Positive cognitive effects of acute donepezil can be observed in various cognitive domains including mood, but its full nootropic potential is more clearly found close to theoretical peak-plasma concentration.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/651/CN-00720651/frame.html>

Record #239 of 370 

ID: CN-00699249

AU: Yancheva S

AU: Ihl R

AU: Nikolova G

AU: Panayotov P

AU: Schlaefke S

AU: Hoerr R

TI: Ginkgo biloba extract EGb 761(R), donepezil or both combined in the treatment of Alzheimer's disease with neuropsychiatric features: a randomised, double-blind, exploratory trial.

SO: Aging & mental health

YR: 2009

VL: 13

NO: 2

PG: 183-90

PM: PUBMED 19347685

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [physiopathology] [psychology];Bulgaria;Double-Blind Method;Drug Therapy, Combination;Ginkgo biloba;Indans [administration & dosage] [pharmacology] [therapeutic use];Nootropic Agents [administration & dosage] [therapeutic use];Outcome Assessment (Health Care);Piperidines [administration & dosage] [pharmacology] [therapeutic use];Plant Extracts [administration & dosage] [pharmacology] [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-COMP MED: SR-DEMENTIA

DOI: 10.1080/13607860902749057

AB: OBJECTIVE: This randomised, double-blind exploratory trial was undertaken to compare treatment effects and tolerability of EGb 761(R), donepezil and combined treatment in patients with AD and neuropsychiatric features. METHOD: We enrolled 96 outpatients, aged 50 years or above, who met the NINCDS/ADRDA criteria for probable AD, scored below 36 on the TE4D, a screening test for dementia, below 6 on the Clock-Drawing Test (CDT) and between 9 and 23 on the SKT, a cross-culturally validated cognitive test battery. They scored at least five on the 12-item Neuropsychiatric Inventory (NPI). EGb 761(R) (240 mg per day), donepezil (initially 5 mg, after 4 weeks 10 mg per day) or EGb 761(R) and donepezil combined (same doses) were administered for 22 weeks. RESULTS: Changes from baseline to week 22 and response rates were similar for all three treatment groups with respect to all outcome measures (SKT, NPI, total score and activities-of-daily-living sub-score of the Gottfries-Br ne-Steen Scale, Hamilton Rating Scale for Depression, CDT and Verbal Fluency Test). An apparent tendency in favour of combination treatment warrants further scrutiny. Compared to donepezil mono-therapy, the adverse event rate was lower under EGb 761(R) treatment and even under the combination treatment. CONCLUSION: These exploratory findings helped to develop three hypotheses that will have to be proven in further studies: (1) there is no significant difference in the efficiency between EGb 761(R) and donepezil, (2) a combination therapy will be superior to a mono-therapy with one of both substances and (3) there will be less side effects under a combination therapy than under mono-therapy with donepezil.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/249/CN-00699249/frame.html>

Record #240 of 370



ID: CN-00683221

AU: Petrella JR

AU: Prince SE

AU: Krishnan S

AU: Husn H

AU: Kelley L

AU: Doraiswamy PM

TI: Effects of donepezil on cortical activation in mild cognitive impairment: a pilot double-blind placebo-controlled trial using functional MR imaging.

SO: AJNR. American journal of neuroradiology

YR: 2009

VL: 30

NO: 2

PG: 411-6

PM: PUBMED 19001543

PT: Controlled Clinical Trial; Journal Article; Multicenter Study; Research Support, Non-U.S. Gov't

KY: Cerebral Cortex [drug effects] [physiology];Cognition Disorders [drug therapy] [physiopathology];Double-Blind Method;Indans [administration & dosage];Magnetic Resonance Imaging;Memory [drug effects] [physiology];Nootropic Agents [administration & dosage];Pilot Projects;Piperidines [administration & dosage];Placebos;Severity of Illness Index;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.3174/ajnr.A1359

AB: BACKGROUND AND PURPOSE: Cholinesterase-inhibitor therapy is approved for treatment of Alzheimer disease; however, application in patients with mild cognitive impairment (MCI) is still under active investigation. The purpose of this study was to determine the effect of such

therapy on the neural substrates underlying memory processing in subjects with MCI by using functional MR imaging (fMRI). MATERIALS AND METHODS: Thirteen subjects with MCI (mean age, 68 +/- 6.9 years) enrolled in a multicenter double-blind placebo-controlled trial testing the clinical efficacy of the cholinesterase-inhibitor, donepezil, were studied with fMRI at baseline and following 12 or 24 weeks of therapy (single-site pilot study). The cognitive paradigm was delayed-response visual memory for novel faces. Within-group 1-sample t tests were performed on the donepezil and placebo groups at baseline and at follow-up. A repeated-measures analysis of variance design was used to look for a Treatment Group x Time interaction showing a significant donepezil- but not placebo-related change in blood oxygen level-dependent response during the course of the study. RESULTS: At baseline, both groups showed multiple areas of activation, including the bilateral dorsolateral prefrontal cortex, fusiform gyrus, and anterior cingulate cortex. On follow-up, the placebo group demonstrated a decreased extent of dorsolateral prefrontal activation, whereas the donepezil group demonstrated an increased extent of activation in the ventrolateral prefrontal cortex. Interaction demonstrated significant donepezil- but not placebo-related change in the left inferior frontal gyrus. CONCLUSIONS: Despite the limitations inherent to a pilot study of a small sample, our results point to specific cortical substrates underlying the actions of donepezil, which can be tested in future studies.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/221/CN-00683221/frame.html>

Record #241 of 370



ID: CN-00703597

AU: Homma A

AU: Imai Y

AU: Tago H

AU: Asada T

AU: Shigeta M

AU: Iwamoto T

AU: Takita M

AU: Arimoto I

AU: Koma H

AU: Takase T

AU: Ohbayashi T

TI: Long-term safety and efficacy of donepezil in patients with severe Alzheimer's disease: results from a 52-week, open-label, multicenter, extension study in Japan.

SO: Dementia and geriatric cognitive disorders

YR: 2009

VL: 27

NO: 3

PG: 232-9

PM: PUBMED 19246907

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [psychology];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Double-Blind Method;Indans [adverse effects] [therapeutic use];Nootropic Agents [adverse effects] [therapeutic use];Piperidines [adverse effects] [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1159/000203887

AB: BACKGROUND/AIMS: A 6-month, randomized, double-blind, placebo-controlled study was extended to evaluate long-term safety and efficacy of donepezil in community-dwelling Japanese patients with severe Alzheimer's disease (AD). METHODS: 189 patients were enrolled from the double-blind study into a 52-week, open-label extension study. After a 2- to 8-week washout, donepezil was escalated within 6 weeks to 10 mg/day. Main outcomes were Severe Impairment Battery (SIB), Alzheimer's Disease Cooperative Study-Activities of Daily Living scale for severe AD (ADCS-ADL-sev) and Behavioral Pathology in Alzheimer's Disease Rating Scale (BEHAVE-AD). Safety parameters were monitored throughout. RESULTS: Overall, mean change from extension study baseline in SIB scores improved until week 24; however, scores were influenced by prior treatment during the double-blind study and by length of washout. Patients treated with donepezil retained some treatment benefits after a washout of 2-4 weeks but lost all treatment benefits after a washout of 4-8 weeks. There was no change in ADCS-ADL-sev or BEHAVE-AD scores. Adverse events were consistent with the known donepezil safety profile. CONCLUSION: Donepezil is effective and safe for symptomatic treatment of severe AD for at least 1 year. Patients who receive donepezil 10 mg daily with little or no interruption achieve the best long-term outcome.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/597/CN-00703597/frame.html>

Record #242 of 370



ID: CN-00721650

AU: Kim YW

AU: Kim DY

AU: Shin JC

AU: Park CI

AU: Lee JD

TI: The changes of cortical metabolism associated with the clinical response to donepezil therapy in traumatic brain injury.

SO: Clinical neuropharmacology

YR: 2009

VL: 32

NO: 2

PG: 63-8

PM: PUBMED 18978490

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Brain Injuries [drug therapy] [pathology];Cerebral Cortex [drug effects] [metabolism];Drug Administration Schedule;Fluorodeoxyglucose F18 [diagnostic use];Follow-Up Studies;Indans [pharmacology] [therapeutic use];Mental Status Schedule;Neuropsychological Tests;Nootropic Agents [pharmacology] [therapeutic use];Piperidines [pharmacology] [therapeutic use];Positron-Emission Tomography [methods];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA: SR-INJ

DOI: 10.1097/WNF.0B013E31816F1BC1

AB: OBJECTIVES: To determine the effects of treatment with donepezil on cortical metabolism in patients with traumatic brain injury using F-fluorodeoxyglucose positron emission tomography. METHODS: Twenty-six patients with cognitive impairment after traumatic brain injury were enrolled and randomly assigned into the donepezil-treated group and the control group. There was no significant difference between 2 groups in age, sex, education, and postinjury duration. Donepezil 5 mg was administered daily for 3 weeks and then 10 mg/d for 3 weeks to patients in the experimental groups. For both groups, we evaluated cognitive function with Mini-Mental State Examination, Wechsler Memory Test, Boston Naming Test,

Colored Progressive Matrices upon initial evaluation and at the 6-week follow-up. An 18F-fluorodeoxyglucose positron emission tomography of the brain was performed before and after 6 weeks of the donepezil-treated group. Effects of donepezil treatment on cortical metabolism were analyzed using Statistical Parametric Mapping software (Institute of Neurology, University College London, UK). RESULTS: There was no significance difference between the 2 groups in initial evaluation of cognitive functions. After 6 weeks, compared with the control group, donepezil-treated group showed enhanced cognitive functions ($P < 0.05$), and 18F-fluorodeoxyglucose positron emission tomography showed a statistically significant increase in the cerebral cortical metabolism for both of the frontal, parietal, occipital, and temporal cortices ($P < 0.01$) which are the key role of attention and object naming. CONCLUSIONS: Cholinergic augmentation by donepezil therapy in traumatic brain injury shows a cortical metabolic effect on the both of the frontal, parietal, occipital, and temporal cortices associated with clinical response to treatment.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/650/CN-00721650/frame.html>

Record #243 of 370



ID: CN-00697687

AU: Lu PH

AU: Edland SD

AU: Teng E

AU: Tingus K

AU: Petersen RC

AU: Cummings JL

TI: Donepezil delays progression to AD in MCI subjects with depressive symptoms.

SO: Neurology

YR: 2009

VL: 72

NO: 24

PG: 2115-21

PM: PUBMED 19528519

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [prevention & control] [psychology];Antioxidants [administration & dosage];Brain [drug effects] [metabolism] [physiopathology];Cholinesterase Inhibitors [administration & dosage];Cognition Disorders [complications] [drug therapy] [psychology];Depressive Disorder [complications] [physiopathology];Disease Progression;Double-Blind Method;Drug Therapy, Combination;Indans [administration & dosage];Neuropsychological Tests;Piperidines [administration & dosage];Placebos;Severity of Illness Index;Time Factors;Tocopherols [administration & dosage];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1212/WNL.0b013e3181aa52d3

AB: OBJECTIVE: To determine whether the presence of depression predicts higher rate of progression to Alzheimer disease (AD) in patients with amnesic mild cognitive impairment (aMCI) and whether donepezil treatment beneficially affect this relationship. METHODS: The study sample was composed of 756 participants with aMCI from the 3-year, double-blind, placebo-controlled Alzheimer's Disease Cooperative Study drug trial of donepezil and vitamin E. Beck Depression Inventory (BDI) was used to assess depressive symptoms at baseline and participants were followed either to the end of study or to the primary endpoint of progression to probable or possible AD. RESULTS: Cox proportional hazards regression, adjusted for age at baseline, gender, apolipoprotein genotype, and NYU paragraph delayed recall score, showed that higher BDI scores were associated with progression to AD ($p = 0.03$). The sample was stratified into depressed (BDI score ≥ 10 ; $n = 208$) and nondepressed (BDI < 10 ; $n = 548$) groups. Kaplan-Meier analysis showed that among the depressed subjects, the proportion progressing to AD was lower for the donepezil group than the combined vitamin E and placebo groups at 1.7 years ($p = 0.023$), at 2.2 years ($p = 0.025$), and remained marginally lower at 2.7 years ($p = 0.070$). The survival curves among the three treatment groups did not differ within the nondepressed participants. CONCLUSIONS: Results suggest that depression is predictive of progression from amnesic mild cognitive impairment (aMCI) to Alzheimer disease (AD) and treatment with donepezil delayed progression to AD among depressed subjects with aMCI. Donepezil appears to modulate the increased risk of AD conferred by the presence of depressive symptoms.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/687/CN-00697687/frame.html>



ID: CN-00683735

AU: Nordberg A

AU: Darreh-Shori T

AU: Peskind E

AU: Soininen H

AU: Mousavi M

AU: Eagle G

AU: Lane R

TI: Different cholinesterase inhibitor effects on CSF cholinesterases in Alzheimer patients.

SO: Current Alzheimer research

YR: 2009

VL: 6

NO: 1

PG: 4-14

PM: PUBMED 19199870


PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Acetylcholinesterase [cerebrospinal fluid];Alzheimer Disease [cerebrospinal fluid] [drug therapy] [enzymology];Brain [drug effects] [enzymology] [physiopathology];Butyrylcholinesterase [cerebrospinal fluid];Cholinesterase Inhibitors [pharmacology] [therapeutic use];Cholinesterases [cerebrospinal fluid];Down-Regulation [drug effects] [physiology];Enzyme-Linked Immunosorbent Assay;Galantamine [pharmacology] [therapeutic use];Indans [pharmacology] [therapeutic use];Phenylcarbamates [pharmacology] [therapeutic use];Piperidines [pharmacology] [therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

AB: BACKGROUND: The current study aimed to compare the effects of different cholinesterase inhibitors on acetylcholinesterase (AChE) and butyrylcholinesterase (BuChE) activities and protein levels, in the cerebrospinal fluid (CSF) of Alzheimer disease (AD) patients. METHODS AND FINDINGS: AD patients aged 50-85 years were randomized to open-label treatment with oral rivastigmine, donepezil or galantamine for 13 weeks. AChE and BuChE activities were assayed by Ellman's colorimetric method. Protein levels were assessed by enzyme-linked immunosorbent assay (ELISA). Primary analyses were based on the Completer population

(randomized patients who completed Week 13 assessments). 63 patients were randomized to treatment. Rivastigmine was associated with decreased AChE activity by 42.6% and decreased AChE protein levels by 9.3%, and decreased BuChE activity by 45.6% and decreased BuChE protein levels by 21.8%. Galantamine decreased AChE activity by 2.1% and BuChE activity by 0.5%, but increased AChE protein levels by 51.2% and BuChE protein levels by 10.5%. Donepezil increased AChE and BuChE activities by 11.8% and 2.8%, respectively. Donepezil caused a 215.2% increase in AChE and 0.4% increase in BuChE protein levels. Changes in mean AChE-Readthrough/Synaptic ratios, which might reflect underlying neurodegenerative processes, were 1.4, 0.6, and 0.4 for rivastigmine, donepezil and galantamine, respectively. CONCLUSION: The findings suggest pharmacologically-induced differences between rivastigmine, donepezil and galantamine. Rivastigmine provides sustained inhibition of AChE and BuChE, while donepezil and galantamine do not inhibit BuChE and are associated with increases in CSF AChE protein levels. The clinical implications require evaluation.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/735/CN-00683735/frame.html>

Record #245 of 370 

ID: CN-00706322

AU: Shah HJ

AU: Kundlik ML

AU: Pandya A

AU: Prajapati S

AU: Subbaiah G

AU: Patel CN

AU: Patel DM

AU: Suhagia BN

AU: Suhagiya BN

TI: A rapid and specific approach for direct measurement of donepezil concentration in human plasma by LC-MS/MS employing solid-phase extraction.

SO: Biomedical chromatography

YR: 2009

VL: 23

NO: 2

PG: 141-51

PM: PUBMED 18823072

PT: Journal Article; Randomized Controlled Trial

KY: Anticoagulants [metabolism];Cholinesterase Inhibitors [administration & dosage] [blood] [pharmacokinetics];Chromatography, Liquid;Citalopram [analysis];Drug Stability;Indans [administration & dosage] [blood] [pharmacokinetics];Linear Models;Piperidines [administration & dosage] [blood] [pharmacokinetics];Reference Standards;Reproducibility of Results;Sensitivity and Specificity;Solid Phase Extraction;Spectrometry, Mass, Electrospray Ionization;Tandem Mass Spectrometry;Adult[checkword];Humans[checkword];Male[checkword]

DOI: 10.1002/bmc.1095

AB: A selective, rapid and simple liquid chromatography-tandem mass spectrometry (LC-MS/MS) method is described for assay of donepezil in human plasma using escitalopram as an internal standard. Chromatographic separation was achieved on a Betabasic-C(8), 5 microm, 100 x 4.6 mm column using methanol:water:formic acid (90:9.97:0.03, v/v/v) as mobile phase. Detection of donepezil and internal standard was achieved by ESI MS/MS in positive ion mode using 380.20/91.10 and 325.13/262.00 transitions, respectively. The linearity over the concentration range of 0.15-50 ng/mL for donepezil was obtained and the lower limit of quantification was 0.15 ng/mL. For each level of quality control samples, inter-day and intra-day precisions (RSD) were < or =8.92 and 10.35% and accuracy (%RE) were < or =7.33% and 9.33%, respectively. The recovery was more than 88.50% for both donepezil and internal standard by solid-phase extraction, eliminating evaporation and reconstitution steps.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/322/CN-00706322/frame.html>

Record #246 of 370



ID: CN-00703538

AU: Peng XW

AU: Dong KL

TI: [Clinical observation on acupuncture combined with Yizhi Jiannao granules for treatment of Alzheimer's disease].

SO: Zhongguo zhen jiu [Chinese acupuncture & moxibustion]

YR: 2009

VL: 29

NO: 4

PG: 269-71

PM: PUBMED 19565731

PT: English Abstract; Journal Article; Randomized Controlled Trial

KY: Acupuncture Points;Acupuncture Therapy [methods];Administration, Oral;Alzheimer Disease [psychology] [therapy];Combined Modality Therapy;Drugs, Chinese Herbal [administration & dosage] [therapeutic use];Indans [administration & dosage] [therapeutic use];Nootropic Agents [administration & dosage] [therapeutic use];Piperidines [administration & dosage] [therapeutic use];Quality of Life;Treatment Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-COMPAMED: SR-DEMENTIA

AB: OBJECTIVE: To observe clinical therapeutic effect of acupuncture combined with Yizhi Jiannao Granules for treatment of Alzheimer's disease and its effects on intelligence, daily life and social activity ability. METHODS: Eighty-four cases were randomly divided into 3 groups, 28 cases in each group. The combined acupuncture and medication group was treated with acupuncture at Baihui (GV 20), Sishencong (EX-HN 1), Dazhui (GV 14), Guanyuan (CV 4), etc. and oral administration of Yizhi Jiannao Granules; the Chinese herb group was treated with Yizhi Jiannao Granules, and the western medicine group with oral administration of Aricept. The scores for the Mini-Mental State Examination (MMSE), Ability of Daily Life (ADL) and the therapeutic effects were assessed and compared before treatment and after treatment for 12 weeks among the groups. RESULTS: After treatment, the scores for MMSE and ADL were improved in the combined acupuncture and medication group, the Chinese herb group and the western medicine group, which were better in the combined acupuncture and medication group ($P < 0.05$). The total effective rate of 85.7% in the combined acupuncture and medication group was better than 71.4% in the Chinese herb group and 67.9% in the western medicine group. CONCLUSION: Acupuncture combined with Yizhi Jiannao Granules has a significant therapeutic effect on Alzheimer's disease, which is better than that of Yizhi Jiannao Granules or Aricept.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/538/CN-00703538/frame.html>

Record #247 of 370



ID: CN-00714119

AU: Anon


TI: [Public title] Safety and efficacy study evaluating dimebon in patients with mild to moderate Alzheimer's disease on donepezil CONCERT; [Scientific title] CONCERT: A phase 3 multicenter, randomized, placebo-controlled, double-blind twelve-month safety and efficacy study evaluating dimebon in patients with mild-to-moderate Alzheimer's disease on donepezil

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/119/CN-00714119/frame.html>

Record #248 of 370 

ID: CN-00714344

AU: Anon


TI: [Public title] A study of RO5313534 as add-on to donepezil treatment in patients with mild to moderate Alzheimer's disease; [Scientific title] A dose-ranging, randomized, double-blind, placebo-controlled study of the effect of RO5313534, used as add-on therapy to donepezil, on cognitive function in patients with mild to moderate symptoms of Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/344/CN-00714344/frame.html>

Record #249 of 370 

ID: CN-00724613

AU: Anon


TI: [Public title] Donepezil in early dementia associated with Parkinson's disease; [Scientific title] Multicentre UK study of the acetylcholinesterase inhibitor donepezil in early dementia associated with Parkinson's disease

SO: ISRCTN Register [<http://www.controlled-trials.com>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/613/CN-00724613/frame.html>

Record #250 of 370 

ID: CN-00738487

AU: Anon


TI: [Public title] Lu AE58054 added to donepezil for the treatment for moderate Alzheimer's disease; [Official/Scientific title] Randomised, double-blind, parallel-group, placebo-controlled, fixed-dose study of Lu AE58054 in patients with moderate Alzheimer's disease treated with donepezil

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/487/CN-00738487/frame.html>

Record #251 of 370 

ID: CN-00738468

AU: Anon

TI: [Public title] A brief study to evaluate the safety, tolerability, and blood levels of multiple doses of PF-044467943 or placebo in combination with donepezil in subjects with mild to moderate Alzheimer's disease; [Official/Scientific title] A phase 1, double-blind, placebo-controlled, sponsor open, randomized, multiple dose study to evaluate the safety, tolerability, and pharmacokinetics of PF-04447943 in mild to moderate Alzheimer's disease subjects on stable donepezil therapy

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/468/CN-00738468/frame.html>

Record #252 of 370



ID: CN-00721752

AU: Sadowsky CH

AU: Dengiz A

AU: Olin JT

AU: Koumaras B

AU: Meng X

AU: Brannan S

TI: Switching from donepezil tablets to rivastigmine transdermal patch in Alzheimer's disease.

SO: American journal of Alzheimer's disease and other dementias

YR: 2009

VL: 24

NO: 3

PG: 267-75

PM: PUBMED 19293130

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't


KY: Administration, Cutaneous; Alzheimer Disease [drug therapy]; Appetite; Cholinesterase Inhibitors [therapeutic use]; Constipation [epidemiology]; Drug Administration Schedule; Electrocardiography; Indans [therapeutic use]; Nausea [epidemiology]; Phenylcarbamates [therapeutic use]; Piperidines [therapeutic use]; Prospective Studies; Time Factors; Aged[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

CC: SR-DEMENTIA

DOI: 10.1177/1533317509333037

AB: OBJECTIVE: Evaluate safety and tolerability of switching from donepezil to rivastigmine transdermal patch in patients with mild to moderate Alzheimer's disease. METHODS: Prospective, parallel-group, open-label study to evaluate immediate or delayed switch from 5-10 mg/day donepezil to 4.6 mg/24 h rivastigmine following a 4-week treatment period. RESULTS: Rates of discontinuation due to any reason or adverse events were similar between groups. Incidences of gastrointestinal adverse events were 3.8% in the immediate and 0.8% in the delayed switch group. No patients discontinued secondary to nausea and vomiting. Discontinuations due to application site reactions were low (2.3%). Asymptomatic bradycardia was more common following the immediate switch (2.3% vs 0%); however, these patients had coexisting cardiac comorbidities. CONCLUSION: Both switch strategies were safe and well tolerated. The majority of patients may be able to switch directly to rivastigmine patches without a withdrawal period. Appropriate clinical judgment should be used for patients with existing bradycardia or receiving beta blockers.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/752/CN-00721752/frame.html>

Record #253 of 370 

ID: CN-00790375

AU: Anon


TI: A dose-ranging, randomized, double-blind , placebo-controlled study of the effect of RO5313534, used as add-on therapy to donepezil, on cognitive function in patients with mild to moderate symptoms of Alzheimer's disease

SO: CentreWatch [www.centrewatch.com]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/375/CN-00790375/frame.html>

Record #254 of 370 

ID: CN-00744265

AU: Pietrzak RH

AU: Maruff P

AU: Snyder PJ

TI: Methodological improvements in quantifying cognitive change in clinical trials: An example with single-dose administration of donepezil

SO: Journal of nutrition, health & aging

YR: 2009


VL: 13

NO: 3

PG: 268-73

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/265/CN-00744265/frame.html>

Record #255 of 370 

ID: CN-00756208

AU: Crane PK

AU: Doody RS

TI: 'Donepezil treatment of patients with MCI: a 48-week randomized, placebo-controlled trial':
Comment

SO: Neurology

YR: 2009


VL: 73

NO: 18

PG: 1514-5

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/208/CN-00756208/frame.html>

Record #256 of 370 

ID: CN-00714255

AU: Anon


TI: A multi-centre, double-blind, double-dummy, placebo-controlled, parallel group, randomised, phase lib proof of concept study with 3 oral dose groups of study drug or donepezil during 12 weeks treatment in patients with Alzheimer's disease

SO: UK Clinical Research Network [www.ukcrn.org.uk]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/255/CN-00714255/frame.html>

Record #257 of 370 

ID: CN-00744215

AU: Anon


TI: A dose ranging, randomised, double blind, parallel group placebo-controlled multi-centre study of RO5313534 used as an add-on to donepezil treatment in patients with mild to moderate symptoms of Alzheimer's Disease

SO: UK Clinical Research Network [www.ukcrn.org.uk]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/215/CN-00744215/frame.html>

Record #258 of 370 

ID: CN-00738509

AU: Burn DJ


TI: Multi-centre UK study of the acetylcholinesterase inhibitor donepezil in early dementia associated with Parkinson's disease (MUSTARDD-PD)

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/509/CN-00738509/frame.html>

Record #259 of 370 

ID: CN-00713997

AU: Anon


TI: [Public title] A study to evaluate the effects of MK0249 and an Alzheimer's disease medication on cognitive function in adults with Alzheimer's disease; [Scientific title] A randomized clinical trial to evaluate the single dose acute effects of MK0249 and donepezil on cognitive function in adult patients with Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/997/CN-00713997/frame.html>

Record #260 of 370 

ID: CN-00724719

AU: Anon

TI: Study of donepezil for MCI shows only minor improvement in patients... mild cognitive impairment.

SO: Brown University Geriatric Psychopharmacology Update

YR: 2009


VL: 13

NO: 8

PG: 1

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/719/CN-00724719/frame.html>

Record #261 of 370 

ID: CN-00764537

AU: Sukys-Claudino L

AU: Moraes W

AU: Poyares D

AU: Tufik S

TI: Donepezil treatment for sleep apnea in non-demented patients [Abstract]

SO: Sleep medicine

YR: 2009

VL: 10


NO: Suppl 2

PG: S79

CC: SR-AIRWAYS

AB: 3rd International Congress on Sleep Medicine - 12th Brazilian Congress on Sleep Medicine
World Association of Sleep Medicine Sao Paulo Brazil

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/537/CN-00764537/frame.html>

Record #262 of 370 

ID: CN-00834226

AU: Moraes W

AU: Sukys-Claudino L

AU: Poyares D

AU: Tufik S

TI: Donepezil treatment for sleep apnea: preliminary results [Abstract]

SO: Sleep

YR: 2009

VL: 32

NO: Suppl

PG: A177 [0537]

CC: SR-AIRWAYS

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/226/CN-00834226/frame.html>

Record #263 of 370



ID: CN-00724600

AU: Hatoum HT

AU: Thomas SK

AU: Lin S-J

AU: Lane R

AU: Bullock R

TI: Predicting time to nursing home placement based on activities of daily living scores - A modelling analysis using data on Alzheimer's disease patients receiving rivastigmine or donepezil.

SO: Journal of medical economics

YR: 2009

VL: 12

NO: 2

PG: 98-103

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/600/CN-00724600/frame.html>

Record #264 of 370



ID: CN-00738331

AU: Lisi D

TI: Response to 'Results, rhetoric, and randomized trials: the case of donepezil'.[comment]

YR: 2009

VL: 57

NO: 7

PG: 1317-8

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/331/CN-00738331/frame.html>

Record #265 of 370



ID: CN-00726642

AU: Grasing K

AU: Mathur D

AU: Newton TF

AU: Desouza C

TI: Donepezil treatment and the subjective effects of intravenous cocaine in dependent individuals

SO: Drug and alcohol dependence

YR: 2009

PM: PUBMED 19836169

CC: SR-ADDICTN

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/642/CN-00726642/frame.html>

Record #266 of 370



ID: CN-00714257

AU: Anon

TI: CONCERT: a phase 3 multicenter, randomized, placebo-controlled, double-blind twelve-month safety and efficacy study evaluating dimebon in patients with mild-to-moderate Alzheimer's disease on donepezil

SO: UK Clinical Research Network [www.ukcrn.org.uk]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/257/CN-00714257/frame.html>

Record #267 of 370



ID: CN-00691777

AU: Hornung OP

AU: Regen F

AU: Dorn H

AU: Anghelescu I

AU: Kathmann N

AU: Schredl M

AU: Danker-Hopfe H

AU: Heuser I

TI: The effects of donepezil on postlearning sleep EEG of healthy older adults

SO: Pharmacopsychiatry

YR: 2009


VL: 42

NO: 1

PG: 9-13

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/777/CN-00691777/frame.html>

Record #268 of 370 

ID: CN-00724544

AU: Anon


TI: [Public title] Donepezil and the risk of falls in seniors with cognitive impairment; [Official title] Can cognitive enhancers reduce the risk of falls in older people with mild cognitive impairment? A randomized controlled trial

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/544/CN-00724544/frame.html>

Record #269 of 370 

ID: CN-00714278

AU: Anon

TI: A Phase III, 7 days randomised, double blind, placebo-controlled, parallel group study to assess efficacy of donepezil, for reducing the symptoms of post-operative delirium after an elective total hip or knee replacement in patients over 65 years old

SO: UK Clinical Research Network [www.ukcrn.org.uk]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/278/CN-00714278/frame.html>

Record #270 of 370



ID: CN-00680883

AU: Ogunmefun A

AU: Hasnain M

AU: Alam A

AU: Osuala T

AU: Regenold WT

TI: Effect of donepezil on tardive dyskinesia.

SO: Journal of clinical psychopharmacology

YR: 2009

VL: 29

NO: 1

PG: 102-4

PM: PUBMED 19142126

PT: Letter; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Antipsychotic Agents [adverse effects];Cholinesterase Inhibitors [therapeutic use];Cross-Over Studies;Double-Blind Method;Dyskinesia, Drug-Induced [drug therapy] [etiology] [physiopathology];Indans [therapeutic use];Piperidines [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-SCHIZ

DOI: 10.1097/JCP.0b013e3181934475

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/883/CN-00680883/frame.html>

Record #271 of 370



ID: CN-00705879

AU: Davis ML

AU: Barrett AM

TI: Selective benefit of donepezil on oral naming in Alzheimer's disease in men compared to women.

SO: CNS spectrums

YR: 2009

VL: 14

NO: 4

PG: 175-6

PM: PUBMED 19407728

PT: Comparative Study; Letter; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Alzheimer Disease [drug therapy] [psychology];Double-Blind Method;Indans [therapeutic use];Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Psychiatric Status Rating Scales;Psychomotor Performance [drug effects];Sex Characteristics;Female[checkword];Humans[checkword];Male[checkword]

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/879/CN-00705879/frame.html>

Record #272 of 370



ID: CN-00759120

AU: Modrego PJ

AU: Fayed N

AU: Ettea JM

AU: Rios C

AU: Pina MA

AU: Sarasa M

TI: Memantine versus donepezil in mild to moderate Alzheimer's disease. A randomized trial with magnetic resonance spectroscopy

SO: Neurology

YR: 2009

VL: 72

NO: 11 Suppl 3

PG: A298, Abstract no: P06.064

CC: HS-NEUROMUSC: HS-HANDSRCH

AB: 61st Annual Meeting of the American Academy of Neurology, 25 April-2 May 2009, Seattle, USA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/120/CN-00759120/frame.html>

Record #273 of 370



ID: CN-00714277

AU: Anon

TI: [Public title] Study comparing 3 dosage levels of SAM-531 in outpatients with mild to moderate Alzheimer disease; [Scientific title] A 52-week, 2-period, multicenter, randomized, double-blind, donepezil-referenced, placebo-controlled, efficacy, and safety study of 3 dosage levels of SAM-531 in outpatients with mild to moderate Alzheimer disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/277/CN-00714277/frame.html>

Record #274 of 370



ID: CN-00714090

AU: Yancheva S Ihl R Nikolova G Panayotov P Schlaefke S Hoerr R

TI: Ginkgo biloba extract EGb 761, donepezil or both combined in the treatment of Alzheimer's disease with neuropsychiatric features: a randomised, double-blind, exploratory trial

SO: Aging & mental health

YR: 2009

VL: 13

NO: 2

PG: 183-90

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/090/CN-00714090/frame.html>

Record #275 of 370



ID: CN-00726659

AU: Grasing K

AU: Mathur D

AU: Newton TF

AU: DeSouza C

TI: The acetylcholinesterase inhibitor donepezil modifies cocaine-induced cardiovascular and subjective effects


SO: Proceedings of the 71th Annual Scientific Meeting of the College on Problems of Drug Dependence; 2009 June 20-25; Reno/Sparks, Nevada, USA

YR: 2009

PG: 50

CC: SR-ADDICTN

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/659/CN-00726659/frame.html>

Record #276 of 370 

ID: CN-00738421

AU: Anon


TI: [Public title] 4 week, safety and tolerability study in patients with mild to moderate Alzheimer's disease (ROBIN); [Scientific title] Safety, tolerability and pharmacokinetics of 3 dose regimens of AZD1446 vs. placebo as an add-on treatment to donepezil: a multi-centre, double-blind, randomised, placebo controlled, parallel group phase IIa study in patients with mild to moderate Alzheimer's disease during 4 weeks of treatment

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2009

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/421/CN-00738421/frame.html>

Record #277 of 370 

ID: CN-00752164

AU: Hilbert A

AU: Dierk JM

AU: Conradt M

AU: Schlumberger P

AU: Hinney A

AU: Hebebrand J

AU: Rief W

TI: Causal attributions of obese men and women in genetic testing: implications of genetic/biological attributions.

SO: Psychology & health

YR: 2009

VL: 24

NO: 7

PG: 749-61

PM: PUBMED 20205024

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Causality;Genetic Testing;Obesity [etiology] [genetics];Questionnaires;Receptor, Melanocortin, Type 4 [blood];Risk Assessment [methods];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-ENDOC

DOI: 10.1080/08870440801947787

AB: The present study sought to investigate genetic/biological attributions of obesity, their associations with a predisposition to obesity and their crosssectional and longitudinal implications for weight regulation in obese individuals presenting for genetic testing and counselling. A total of 421 obese men and women underwent psychological and anthropometric assessment and a mutation screen of the melanocortin-4 receptor gene. At study entry, women revealed more genetic/biological attributions than men on the Revised Illness Perception Questionnaire adapted to obesity (86.2% versus 59.7%). Genetic/biological attributions of obesity were associated in both sexes with a family history of obesity, assessed through Stunkard's Figure Rating Scale. In both sexes, genetic/biological attributions were unrelated to weight regulation beliefs and behaviour (i.e. self-efficacy, controllability beliefs, restrained eating and physical activity), assessed through standardised questionnaires or interview at baseline and at six-month follow-up. In addition, causal attributions and weight regulation beliefs and behaviour were not predictive of body mass index at six-month follow-up. Overall, the results indicate that causal attributions of obesity to genetic/biological factors in obese individuals presenting for genetic screening and counselling are crosssectionally and longitudinally unrelated to weight regulation and longer-term weight outcome. Those who attribute their obesity to genetic/biological factors likely have a familial obesity risk.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/164/CN-00752164/frame.html>

Record #278 of 370



ID: CN-00751054

AU: Koningsbruggen GM

AU: Das E

TI: Don't derogate this message! Self-affirmation promotes online type 2 diabetes risk test taking.

SO: Psychology & health

YR: 2009

VL: 24

NO: 6

PG: 635-49

PM: PUBMED 20205017

PT: Journal Article; Randomized Controlled Trial

KY: Adaptation, Psychological;Diabetes Mellitus, Type 2 [psychology];Health Behavior;Health Education;Internet;Mass Screening;Netherlands;Risk-Taking;Self Concept;Adult[checkword];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword];Young Adult[checkword]

CC: SR-ENDOC

DOI: 10.1080/08870440802340156

AB: The aim of the present study was to examine whether self-affirmation promotes acceptance of threatening type 2 diabetes information and risk-testing behaviour. In an experimental study (N = 84), we manipulated self-affirmation by allowing participants to affirm a value that was either personally important or unimportant to them, and measured participants' risk level prior to reading threatening type 2 diabetes information. As dependent variables, we measured message derogation, intentions to do an online type 2 diabetes risk test and online risk-testing behaviour. Findings showed that self-affirmation decreased message derogation, increased intentions to do an online risk test and promoted online risk test taking among at-risk participants. Among participants not at-risk, self-affirmation decreased intentions and online risk test taking. Therefore, it is concluded, that for an at-risk population self-affirmation can decrease defensive responses to threatening health information and promote (online) risk test taking for diseases.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/054/CN-00751054/frame.html>

Record #279 of 370



ID: CN-00733996

AU: Taylor VM

AU: Teh C

AU: Lam W

AU: Acorda E

AU: Li L

AU: Coronado G

AU: Yasui Y

AU: Bajdik C

AU: Hislop G

TI: Evaluation of a hepatitis B educational ESL curriculum for Chinese immigrants.

SO: Canadian journal of public health = Revue canadienne de santé publique

YR: 2009

VL: 100

NO: 6

PG: 463-6

PM: PUBMED 20209742


PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: China [ethnology];Curriculum;Emigrants and Immigrants [education];Health Knowledge, Attitudes, Practice;Hepatitis B;Language;Program Evaluation;United States;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

AB: OBJECTIVES: According to recent census data, 1,216,600 Canadians are of Chinese descent, and over 80% of Chinese Canadians are foreign born. Approximately 10% of Chinese immigrants are chronic carriers of hepatitis B, compared with less than 0.5% of the general population. English as a second language (ESL) classes provide ready access for individuals with limited English proficiency who are not reached by English language health education materials and media campaigns. We conducted a group-randomized trial to evaluate the effectiveness of a hepatitis B ESL educational curriculum for Chinese immigrants. METHODS: Five community-

based organizations that provide ESL education in the greater Vancouver area participated in the study. Forty-one ESL classes (which included 325 Chinese students) were randomly assigned to experimental or control status. A follow-up survey, conducted six months after randomization, assessed knowledge about hepatitis B. Generalized estimating equations were used to analyze the data. RESULTS: Follow-up surveys were completed by 298 (92%) of the students. At follow-up, experimental group students were significantly ($p < 0.05$) more likely than control group students to know that immigrants have higher hepatitis B infection rates than people who were born in Canada; hepatitis B can be spread during childbirth, during sexual intercourse and by sharing razors; hepatitis B is not spread by sharing eating utensils; and hepatitis B infection can cause cirrhosis and liver cancer. CONCLUSION: Our findings indicate that ESL curricula can have a positive impact on health knowledge among Chinese immigrants with limited English. Future research should evaluate the effectiveness of ESL curricula for other immigrant groups, as well as other health topics.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/996/CN-00733996/frame.html>

Record #280 of 370 

ID: CN-00720967

AU: Montero-Odasso M

AU: Wells JL

AU: Borrie MJ

AU: Speechley M

TI: Can cognitive enhancers reduce the risk of falls in older people with mild cognitive impairment? A protocol for a randomised controlled double blind trial.

SO: BMC neurology

YR: 2009

VL: 9

PG: 42

PM: PUBMED 19674471

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Accidental Falls [prevention & control];Cholinesterase Inhibitors [therapeutic use];Clinical Protocols;Cognition Disorders [complications] [drug therapy];Community-Based Participatory Research;Double-Blind Method;Gait;Indans [therapeutic use];Patient Selection;Piperidines


[therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-DEMENTIA: SR-INJ: SR-MUSKINJ

DOI: 10.1186/1471-2377-9-42

AB: BACKGROUND: Older adults with cognitive problems have a higher risk of falls, at least twice that of cognitively normal older adults. The consequences of falls in this population are very serious: fallers with cognitive problems suffer more injuries due to falls and are approximately five times more likely to be admitted to institutional care. Although the mechanisms of increased fall risk in cognitively impaired people are not completely understood, it is known that impaired cognitive abilities can reduce attentional resource allocation while walking. Since cognitive enhancers, such as cholinesterase inhibitors, improve attention and executive function, we hypothesise that cognitive enhancers may reduce fall risk in elderly people in the early stages of cognitive decline by improving their gait and balance performance due to an enhancement in attention and executive function. METHOD/DESIGN: Double blinded randomized controlled trial with 6 months follow-up in 140 older individuals with Mild Cognitive Impairment (MCI). Participants will be randomized to the intervention group, receiving donepezil, and to the control group, receiving placebo. A block randomization by four and stratification based on fall history will be performed. Primary outcomes are improvements in gait velocity and reduction in gait variability. Secondary outcomes are changes in the balance confidence, balance sway, attention, executive function, and number of falls. DISCUSSION: By characterizing and understanding the effects of cognitive enhancers on fall risk in older adults with cognitive impairments, we will be able to pave the way for a new approach to fall prevention in this population. This RCT study will provide, for the first time, information regarding the effect of a medication designed to augment cognitive functioning have on the risk of falls in older adults with Mild Cognitive Impairment. We expect a significant reduction in the risk of falls in this vulnerable population as a function of the reduced gait variability achieved by treatment with cognitive enhancers. This study may contribute to a new approach to prevent and treat fall risk in seniors in early stages of dementia. TRIAL REGISTRATION: The protocol for this study is registered with the Clinical Trials Registry, identifier number: NCT00934531 <http://www.clinicaltrials.gov>.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/967/CN-00720967/frame.html>

Record #281 of 370 

ID: CN-00749880

AU: Schmitt FA

AU: Saxton JA

AU: Xu Y

AU: McRae T

AU: Sun Y

AU: Richardson S

AU: Li H

TI: A brief instrument to assess treatment response in the patient with advanced Alzheimer disease.

SO: Alzheimer disease and associated disorders

YR: 2009

VL: 23

NO: 4

PG: 377-83

PM: PUBMED 19571727

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [diagnosis] [drug therapy] [psychology];Double-Blind Method;Indans [therapeutic use];Neuropsychological Tests [standards];Piperidines [therapeutic use];Randomized Controlled Trials as Topic [methods] [psychology];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1097/WAD.0b013e3181ac9cc1

AB: The availability of effective treatments for severe Alzheimer disease (AD) has accentuated the need for brief, simple tools to evaluate treatment response in busy clinical settings for patients with advanced dementia. To develop such a tool, data on 875 patients from 4 double-blind-randomized studies of donepezil in severe AD [Mini-Mental State Examination (MMSE) 0 to 12 inclusive] were pooled and analyzed to identify Severe Impairment Battery (SIB) items, which are sensitive to change over time. Eight of the 51 SIB items were chosen based on effect sizes and relative ease of administration. The resulting SIB-8 was then applied to a validation data set (not used to generate the short form) to characterize its usefulness. The items, Month, Months of Year, Write Name, Sentence, Fluency, Confrontational Naming-Spoon, Using Spoon-Photograph, and Digit Span, were sensitive to change with treatment ($P < 0.0001$) and easy to administer. Baseline SIB-8 scores were correlated with baseline MMSE and full-scale SIB scores, and provided a good distribution of scores in patients at the lower end of the MMSE. The SIB-8 is a brief ($< \text{or} = 3$ min) assessment for patients with severe AD that is sensitive to change and able to detect treatment response.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/880/CN-00749880/frame.html>

Record #282 of 370



ID: CN-00849133

AU: Khedr E

AU: Rothwell JC

AU: Amal E

AU: Ahmed M

AU: Khalifa H

TI: A comparative study: contralateral versus ipsilateral rtms of temporo-parietal cortex for the treatment of chronic tinnitus

SO: 3rd International TRI Tinnitus Conference 2009, Stresa, Italy, June 24-26 2009

YR: 2009

PG: 63

CC: SR-ENT

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/133/CN-00849133/frame.html>

Record #283 of 370



ID: CN-00849131

AU: Heijnen KM

AU: Kleine E

AU: van Dijk

TI: A double-blind cross-over study to evaluate the effect of phase-shift sound therapy on tonal tinnitus

SO: 3rd International TRI Tinnitus Conference 2009, Stresa, Italy, June 24-26 2009

YR: 2009

PG: 33

CC: SR-ENT

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/131/CN-00849131/frame.html>

Record #284 of 370



ID: CN-00730774

AU: Zijlstra GA

AU: Haastregt JC

AU: Ambergen T

AU: Rossum E

AU: Eijk JT

AU: Tennstedt SL

AU: Kempen GI

TI: Effects of a multicomponent cognitive behavioral group intervention on fear of falling and activity avoidance in community-dwelling older adults: results of a randomized controlled trial.

SO: Journal of the American Geriatrics Society

YR: 2009

VL: 57

NO: 11

PG: 2020-8

PM: PUBMED 19793161

XR: EMBASE 2009560323

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Accidental Falls [prevention & control];Adaptation, Psychological;Avoidance Learning;Cognitive Therapy [methods];Fear;Follow-Up Studies;Independent Living [psychology];Netherlands;Psychotherapy, Group [methods];Social

Isolation;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-INJ: SR-MUSKINJ

DOI: 10.1111/j.1532-5415.2009.02489.x

AB: OBJECTIVES: To evaluate the effects of a multicomponent cognitive behavioral intervention on fear of falling and activity avoidance in older adults. DESIGN: Randomized controlled trial. SETTING: Community-dwelling adults in the Netherlands. PARTICIPANTS: Five hundred forty adults aged 70 and older who reported fear of falling and fear-induced activity avoidance (280 intervention, 260 control). INTERVENTION: A multicomponent cognitive behavioral group intervention consisting of eight weekly sessions and a booster session. The sessions were aimed at instilling adaptive and realistic views on falls, reducing fall risk, and increasing activity and safe behavior. MEASUREMENTS: Data on fear of falling, activity avoidance, concerns about falling, perceived control over falling, and daily activity were collected at baseline and at 2, 8, and 14 months. RESULTS: At 2 months, there were significant between-group differences in fear of falling (odds ratio (OR)=0.11; $P<.001$), activity avoidance (OR=0.26; $P<.001$), concerns about falling (adjusted mean difference=-1.51; $P=.02$), and daily activity (adjusted mean difference=0.95; $P=.01$). At 8 months, there were significant between-group differences in all outcomes and at 14 months in fear of falling ($P=.001$), perceived control over falling ($P=.001$), and recurrent fallers ($P=.02$) but not in activity avoidance ($P=.07$), concerns about falling ($P=.07$), daily activity ($P=.24$), or fallers ($P=.08$). CONCLUSION: This multicomponent cognitive behavioral intervention showed positive and durable effects on fear of falling and associated activity avoidance in community-dwelling older adults. Future research should focus on improving intervention uptake and adherence, reaching frailer populations, and determining potential intervention effects on functional outcomes.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/774/CN-00730774/frame.html>

Record #285 of 370



ID: CN-00733136

AU: Haque S

AU: Khan AA

TI: Effects of ulnar deviation of the wrist combined with flexion/extension on the maximum voluntary contraction of grip.

SO: Journal of human ergology

YR: 2009

VL: 38

NO: 1

PG: 1-9

PM: PUBMED 20034313

PT: Journal Article; Randomized Controlled Trial

KY: Analysis of Variance; Biomechanical Phenomena; Cumulative Trauma Disorders [prevention & control]; Forearm [physiology]; Hand Strength [physiology]; Human Engineering; Posture [physiology]; Ulna [physiology]; Wrist Injuries [prevention & control]; Wrist Joint [physiology]; Adult[checkword]; Humans[checkword]; Male[checkword]

AB: Work-related musculoskeletal disorders (WMSDs) is related with the frequency of exertion for repetitive tasks requiring heavy load. Different researchers have reported that a poor posture is very much responsible for WMSD if combined with increased load and/or frequency. In the assembly tasks in different industries involve the gripping very commonly. Therefore in the present study it was tried to find the effect of a wrist posture on grip strength. For design of experiment, subjects, flexion/extension and ulnar deviation of the wrist were taken as independent variables and the dependent variable was maximum voluntary contraction (MVC) of grip. The results showed that the effect of flexion/extension angle, ulnar angle and the subject on MVC grip were highly significant (i.e., $p < 0.001$, 0.001 and 0.002 respectively). The two-way interaction effect of flexion/extension angle of the wrist and the subject on MVC grip was also found significant at $p < 0.001$. The other interaction effects were not found significant. MVC grip was found maximum at the neutral wrist posture.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/136/CN-00733136/frame.html>

Record #286 of 370



ID: CN-00753842

AU: Ahmad J

AU: Khan RA

AU: Ashraf Malik M

TI: Study of Nigella sativa oil in the management of wheeze associated lower respiratory tract illness in children.

SO: African Journal of Pharmacy and Pharmacology

YR: 2009

VL: 3

NO: 5

PG: 248-51

XR: EMBASE 2009266644


PT: Journal: Article

KY: adolescent // adult // article // child // clinical trial // controlled clinical trial // controlled study // disease association // drug effect // female // human // lower respiratory tract // major clinical study // male // patient assessment // peak expiratory flow // preschool child // randomized controlled trial // respiratory tract disease // school child // *wheezing/dt [Drug Therapy] // *essential oil/ct [Clinical Trial] // *essential oil/dt [Drug Therapy] // ipratropium bromide/ct [Clinical Trial] // ipratropium bromide/cb [Drug Combination] // ipratropium bromide/dt [Drug Therapy] // *Nigella sativa extract/ct [Clinical Trial] // *Nigella sativa extract/dt [Drug Therapy] // salbutamol/ct [Clinical Trial] // salbutamol/cb [Drug Combination] // salbutamol/dt [Drug Therapy] // terbutaline/ct [Clinical Trial] // terbutaline/dt [Drug Therapy] // terbutaline/po [Oral Drug Administration]

CC: SR-AIRWAYS: SR-COMP MED

AB: Nigella sativa seeds and its oil had been widely used in traditional medicine (particularly in Unani Medicine) for a wide variety of illnesses including bronchial asthma in adults. The adjuvant effect of N. sativa oil in patients of bronchial asthma has already been reported but, no work had yet been done in very common disease of children called wheeze associated lower respiratory tract illness (wheeze associated LRTI). So In the present study 84 patients of wheeze associated LRTI were investigated for any beneficial role of N. sativa oil in this condition. Control group (41) and test group (43), were administered with Standard treatment and N. sativa oil along with Standard treatment in dose of 0.1 ml/kg/day, respectively. Patients were assessed on 0 (Zero) day and reassessed on 3rd, 7th, 10th and 14th day of treatment by using Pulmonary Index (PI) and Peak Expiratory Flow Rate (PEFR). The PI was reduced more in test group as compared to control group in all days of treatment and difference was statistically significant on 3rd day ($P < 0.05$). The inter-group comparison on 3rd, 7th, 10th and 14th day also showed significant reduction in PI of test group compared to control group ($P < 0.001$). PEFR showed higher improvement in test group compared to control group in all days of treatment, although, here the difference was statistically insignificant ($P > 0.05$). In inter-group comparison, the improvement in PEFR was observed only till 7th day of treatment in the control group but it was upto 14th day of treatment in the test group ($P < 0.0001$). 2008 Academic Journals.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/842/CN-00753842/frame.html>

Record #287 of 370 

ID: CN-00753985

AU: Henderson ST

AU: Vogel JL

AU: Barr LJ

AU: Garvin F

AU: Jones JJ

AU: Costantini LC

TI: Study of the ketogenic agent AC-1202 in mild to moderate Alzheimer's disease: A randomized, double-blind, placebo-controlled, multicenter trial.

SO: Nutrition & metabolism

YR: 2009

VL: 6

PG: 31TN: NCT00142805/ClinicalTrials.gov

XR: EMBASE 2009460801

PT: Journal: Article

KY: adult // aged // allele // *Alzheimer disease/dt [Drug Therapy] // article // Clinical Global Impression scale // clinical trial // cognition // controlled clinical trial // controlled study // dietary intake // disease severity // double blind procedure // drug effect // drug withdrawal // female // gastrointestinal symptom/si [Side Effect] // heterozygote // human // *ketogenesis // major clinical study // male // multicenter study // patient compliance // randomized controlled trial // treatment duration // treatment outcome // treatment response // 3 hydroxybutyric acid/ec [Endogenous Compound] // ac 1202 // apolipoprotein E4/ec [Endogenous Compound] // donepezil/dt [Drug Therapy] // galantamine/dt [Drug Therapy] // ketone body/ec [Endogenous Compound] // memantine/dt [Drug Therapy] // placebo // *trioctanoin/ae [Adverse Drug Reaction] // *trioctanoin/ct [Clinical Trial] // *trioctanoin/dt [Drug Therapy] // *trioctanoin/po [Oral Drug Administration] // unclassified drug

CC: SR-DEMENTIA

DOI: 10.1186/1743-7075-6-31

AB: Background. Alzheimer's disease (AD) is characterized by early and region-specific declines in cerebral glucose metabolism. Ketone bodies are produced by the body during glucose deprivation and are metabolized by the brain. An oral ketogenic compound, AC-1202, was

tested in subjects with probable AD to examine if ketosis could improve cognitive performance. Methods. Daily administration of AC-1202 was evaluated in 152 subjects diagnosed with mild to moderate AD in a US-based, 90-day, randomized, double-blind, placebo-controlled, parallel-group study. Subjects were on a normal diet and continued taking approved AD medications. Primary cognitive end points were mean change from Baseline in the AD Assessment Scale-Cognitive subscale (ADAS-Cog), and global scores in the AD Cooperative Study Clinical Global Impression of Change (ADCS-CGIC). AC-1202 was compared to Placebo in several population groups, including: intention-to-treat (ITT), per protocol, and dosage compliant groups. Results were also stratified by APOE4 carriage status (a predefined analysis based on the epsilon 4 (E4) variant of the apolipoprotein E gene). This trial was registered with ClinicalTrials.gov, registry number NCT00142805, information available at <http://clinicaltrials.gov/ct2/show/NCT00142805>. Results. AC-1202 significantly elevated a serum ketone body (-hydroxybutyrate) 2 hours after administration when compared to Placebo. In each of the population groups, a significant difference was found between AC-1202 and Placebo in mean change from Baseline in ADAS-Cog score on Day 45: 1.9 point difference, $p = 0.0235$ in ITT; 2.53 point difference, $p = 0.0324$ in per protocol; 2.6 point difference, $p = 0.0215$ in dosage compliant. Among participants who did not carry the APOE4 allele (E4(-)), a significant difference was found between AC-1202 and Placebo in mean change from Baseline in ADAS-Cog score on Day 45 and Day 90. In the ITT population, E4(-) participants (N = 55) administered AC-1202 had a significant 4.77 point difference in mean change from Baseline in ADAS-Cog scores at Day 45 ($p = 0.0005$) and a 3.36 point difference at Day 90 ($p = 0.0148$) compared to Placebo. In the per protocol population, E4(-) participants receiving AC-1202 (N = 37) differed from placebo by 5.73 points at Day 45 ($p = 0.0027$) and by 4.39 points at Day 90 ($p = 0.0143$). In the dosage compliant population, E4(-) participants receiving AC-1202 differed from placebo by 6.26 points at Day 45 ($p = 0.0011$, N = 38) and 5.33 points at Day 90 ($p = 0.0063$, N = 35). Furthermore, a significant pharmacologic response was observed between serum -hydroxybutyrate levels and change in ADAS-Cog scores in E4(-) subjects at Day 90 ($p = 0.008$). Adverse events occurred more frequently in AC-1202 subjects, were primarily restricted to the gastrointestinal system, and were mainly mild to moderate in severity and transient in nature. Conclusion. AC-1202 rapidly elevated serum ketone bodies in AD patients and resulted in significant differences in ADAS-Cog scores compared to the Placebo. Effects were most notable in APOE4(-) subjects who were dosage compliant. 2009 Henderson et al.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/985/CN-00753985/frame.html>

Record #288 of 370



ID: CN-00667125

AU: Pelton GH

AU: Harper OL

AU: Tabert MH

AU: Sackeim HA

AU: Scarmeas N

AU: Roose SP

AU: Devanand DP

TI: Randomized double-blind placebo-controlled donepezil augmentation in antidepressant-treated elderly patients with depression and cognitive impairment: a pilot study.

SO: International journal of geriatric psychiatry

YR: 2008

VL: 23

NO: 7

PG: 670-6

PM: PUBMED 18088076

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Antidepressive Agents [therapeutic use];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Cognition Disorders [drug therapy] [psychology];Depressive Disorder [drug therapy] [psychology];Epidemiologic Methods;Indans [adverse effects] [therapeutic use];Neuropsychological Tests;Nootropic Agents [adverse effects] [therapeutic use];Piperidines [adverse effects] [therapeutic use];Sertraline [therapeutic use];Treatment Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]


CC: SR-DEMENTIA: SR-DEPRESSN

DOI: 10.1002/gps.1958

AB: OBJECTIVE: To assess combined antidepressant and cognitive enhancer treatment in elderly patients presenting with depression plus cognitive impairment. METHODS: Twenty-three elderly (>50 years old) depressed, cognitively impaired (DEP-CI) patients participated in a pilot study. We evaluated whether, after 8 weeks of open antidepressant treatment, donepezil HCl (Aricept) would afford added cognitive benefit compared to placebo in a randomized 12-week trial. A subsample continued in an 8-month extension phase of open treatment with donepezil. Neuropsychological testing (NPT) was performed and antidepressant response monitored at baseline and the 8, 20, and 52-week time points. RESULTS: At 8-weeks, the antidepressant response rate was 61% (14/23). Improvement in SRT immediate recall (SRT-IR; e.g. episodic verbal memory) was observed in responders compared to non-responders. During the 12-week, placebo-controlled, donepezil add-on trial, patients on donepezil showed further improvement in SRT-IR versus patients on placebo. In the open extension phase,

patients who continued open donepezil treatment (n = 6) maintained improvement in memory and tended to show an advantage over patients who never received donepezil and were evaluated at the 52-week time point (n = 6). There were no observed significant donepezil effects on non-memory cognitive domains. CONCLUSION: These preliminary findings suggest that addition of a cholinesterase inhibitor (AChEI) following antidepressant medication treatment in elderly Dep-CI patients may improve cognition, and support the need for a confirmatory, larger randomized placebo-controlled trial.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/125/CN-00667125/frame.html>

Record #289 of 370 

ID: CN-00651217

AU: Yesavage JA

AU: Friedman L

AU: Ashford JW

AU: Kraemer HC

AU: Mumenthaler MS

AU: Noda A

AU: Hoblyn J

TI: Acetylcholinesterase inhibitor in combination with cognitive training in older adults.

SO: Journals of gerontology. Series B, Psychological sciences and social sciences

YR: 2008

VL: 63

NO: 5

PG: P288-94

PM: PUBMED 18818443

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, Non-P.H.S.

KY: Cholinesterase Inhibitors [administration & dosage]; Combined Modality Therapy; Double-Blind Method; Indans [administration & dosage]; Memory Disorders [drug therapy]

[therapy];Piperidines [administration & dosage];Psychotherapy
[methods];Aged[checkword];Aged, 80 and
over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle
Aged[checkword]

CC: SR-BEHAVMED: SR-DEMENTIA

AB: To determine if donepezil, an acetylcholinesterase (AChE) inhibitor, improved the assimilation of cognitive training by older adults with memory complaints, we gave 168 nondemented, community-dwelling volunteers with memory complaints either 5 mg of donepezil (Aricept) or placebo daily for 6 weeks in a randomized, double-blind, placebo-controlled trial. The dosage rose to 10 mg daily for another 6 weeks before a 2-week course of cognitive training and was maintained for the remainder of a year. Cognitive training improved performance; donepezil was well tolerated. However, there were no significant benefits of donepezil compared with placebo. An additional dose-ranging study with a starting dose of 5 mg a day suggests that the high dose was not the reason. Physiological tolerance may occur with chronic donepezil treatment and may increase AChE levels; this may be why short-term studies have shown the benefit of AChE inhibitor use in nondemented participants whereas chronic use has failed to enhance cognition.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/217/CN-00651217/frame.html>

Record #290 of 370



ID: CN-00629920

AU: Doody RS

AU: Corey-Bloom J

AU: Zhang R

AU: Li H

AU: Ieni J

AU: Schindler R

TI: Safety and tolerability of donepezil at doses up to 20 mg/day: results from a pilot study in patients with Alzheimer's disease.

SO: Drugs & aging

YR: 2008

VL: 25

NO: 2

PG: 163-74

PM: PUBMED 18257603

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Cholinesterase Inhibitors [administration & dosage] [adverse effects] [pharmacokinetics];Dose-Response Relationship, Drug;Double-Blind Method;Electrocardiography;Indans [administration & dosage] [adverse effects] [pharmacokinetics];Pilot Projects;Piperidines [administration & dosage] [adverse effects] [pharmacokinetics];Psychiatric Status Rating Scales;Psychometrics;Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

AB: BACKGROUND: Donepezil is licensed for the treatment of mild-to-moderate Alzheimer's disease (AD) at doses of 5-10 mg/day and has recently been approved in the US for severe AD. Multiple studies have suggested that donepezil 10 mg/day provides additional cognitive and functional benefits over the 5 mg/day dose. Higher doses of donepezil, if safe and well tolerated, might provide further benefits for patients with AD. OBJECTIVE: To evaluate the safety and tolerability of donepezil at doses of 15 and 20 mg/day. METHOD: A 24-week, randomized, double-blind, placebo-controlled, pilot study conducted at two investigational sites in the US. Enrolled patients (male and female; aged 50-86 years) had a diagnosis of probable AD at the mild-to-moderate stage (Mini-Mental State Examination [MMSE] score 10-26). All patients had been treated with donepezil 10 mg/day for 12-30 months prior to enrolment. Patients (n = 31) were randomized 1 : 1 to receive either a standard dose of donepezil (donepezil 10 mg/day plus placebo 5 mg/day for weeks 1-12; donepezil 10 mg/day plus placebo 10 mg/day for weeks 13-24) or a higher dose of donepezil (donepezil 15 mg/day for weeks 1-12; donepezil 20 mg/day for weeks 13-24). Primary outcome measures were tolerability (as determined by monitoring of discontinuations, dose modifications and adverse events) and safety (as determined by adverse event monitoring, physical examinations, clinical laboratory tests and ECGs). Psychometric measures (Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-cog], MMSE and Clinician's Interview-Based Impression of Change with caregiver information [CIBIC+]) and pharmacokinetic/pharmacodynamic parameters were secondary outcomes. RESULTS: No patients withdrew from the study and there were no serious adverse events or deaths. By week 24, 15 of 16 patients in the higher-dose group tolerated the maximum 20 mg/day dose; one patient had a permanent dose reduction to donepezil 15 mg/day. In the standard-dose group, 14 of 15 patients tolerated donepezil 10 mg/day plus placebo 10 mg/day by the end of the study; one patient had a permanent dose reduction to donepezil 10 mg/day plus placebo 5 mg/day. Temporary dose reductions occurred in two patients (one from each group). Adverse events reported were as expected for donepezil and were all mild to moderate in intensity. Adverse events considered to be possibly

or probably related to treatment were reported for three patients in the standard-dose group and six patients in the higher-dose group. One patient in the higher-dose group had weight loss reported as possibly or probably treatment related. Mean changes on ECGs were not clinically significant in either group, and the incidence of bradycardia was comparable. No treatment difference on any of the psychometric measures was observed between the groups. Pharmacokinetic analyses showed that an increased donepezil dose was associated with an increase in donepezil plasma concentrations from baseline. CONCLUSION: In this small pilot study of patients with mild-to-moderate AD already stabilized on donepezil 10 mg/day, doses of 15 and 20 mg/day of donepezil appeared safe and well tolerated. These results justify initiation of larger clinical trials designed to investigate the efficacy and safety of doses of donepezil higher than 10 mg/day in patients with AD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/920/CN-00629920/frame.html>

Record #291 of 370



ID: CN-00706099

AU: Keefe RS

AU: Malhotra AK

AU: Meltzer HY

AU: Kane JM

AU: Buchanan RW

AU: Murthy A

AU: Sovel M

AU: Li C

AU: Goldman R

TI: Efficacy and safety of donepezil in patients with schizophrenia or schizoaffective disorder: significant placebo/practice effects in a 12-week, randomized, double-blind, placebo-controlled trial.

SO: Neuropsychopharmacology

YR: 2008

VL: 33

NO: 6

PG: 1217-28

PM: PUBMED 17625502

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cholinesterase Inhibitors [therapeutic use]; Clinical Trials as Topic; Cognition Disorders [etiology] [therapy]; Double-Blind Method; Indans [therapeutic use]; Neuropsychological Tests; Piperidines [therapeutic use]; Placebo Effect; Practice (Psychology); Prospective Studies; Psychiatric Status Rating Scales; Psychotic Disorders [complications] [drug therapy]; Schizophrenia [complications] [drug therapy]; Time Factors; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

CC: SR-SCHIZ

DOI: 10.1038/sj.npp.1301499

AB: Altered expression of central muscarinic and nicotinic acetylcholine receptors in hippocampal and cortical regions may contribute to the cognitive impairment exhibited in patients with schizophrenia. Increasing cholinergic activity through the use of a cholinesterase inhibitor (ChEI) therefore represents a possible strategy for cognitive augmentation in schizophrenia. We examined the efficacy and safety of the ChEI donepezil as cotreatment for mild to moderate cognitive impairment in schizophrenia or schizoaffective disorder in a prospective, 12-week, placebo-controlled, double-blind, parallel-group study. In total, 250 patients (18-55 years) with schizophrenia or schizoaffective disorder who were clinically stabilized on risperidone, olanzapine, quetiapine, ziprasidone, or aripiprazole, alone or in combination, were enrolled at 38 outpatient psychiatric clinics in the United States. Patients were randomized to donepezil 5 mg q.d. for 6 weeks then 10 mg q.d. for 6 weeks, or placebo administered as oral tablets. The primary outcome measure was the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) neurocognitive battery composite score. In the intent-to-treat sample (donepezil, n=121; placebo, n=124), both treatments showed improvement in the composite score from baseline to week 12. At week 12, cognitive improvement with donepezil was similar to that with placebo (last-observation-carried-forward effect size, 0.277 vs 0.411; $p=0.1182$) and statistically significantly inferior for the observed-cases analysis (0.257 vs 0.450; $p=0.044$). There was statistically significant improvement in the Positive and Negative Syndrome Assessment Scale negative symptoms score for placebo compared with donepezil, while total and positive symptom scores were similar between both treatments. Statistically significant improvements in positive symptoms score and Clinical Global Impression-Improvement for donepezil compared with placebo were noted at Week 6. Treatment-emergent adverse events (AEs) were observed for 54.5% of donepezil- and 61.3% of placebo-treated patients; most AEs were rated as mild to moderate in severity. Donepezil was safe and well-tolerated but was not effective compared with placebo as a cotreatment for the improvement of cognitive impairment in this patient population. A significant and surprisingly large placebo/practice effect was observed among placebo-treated

patients, and is a serious consideration in future clinical trial study designs for potential cognitive enhancing compounds in schizophrenia.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/099/CN-00706099/frame.html>

Record #292 of 370



ID: CN-00638735

AU: Homma A

AU: Imai Y

AU: Tago H

AU: Asada T

AU: Shigeta M

AU: Iwamoto T

AU: Takita M

AU: Arimoto I

AU: Koma H

AU: Ohbayashi T

TI: Donepezil treatment of patients with severe Alzheimer's disease in a Japanese population: results from a 24-week, double-blind, placebo-controlled, randomized trial.

SO: Dementia and geriatric cognitive disorders

YR: 2008

VL: 25

NO: 5

PG: 399-407

PM: PUBMED 18391486

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [physiopathology];Dose-Response Relationship, Drug;Indans [administration & dosage];Japan;Mental Status Schedule;Neuropsychological Tests;Nootropic Agents [administration & dosage];Piperidines [administration & dosage];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1159/000122961

AB: BACKGROUND/AIMS: A 24-week, randomized, parallel-group, double-blind placebo-controlled study was conducted to evaluate the efficacy and tolerability of donepezil in severe Alzheimer's disease (AD). METHODS: Patients with severe AD (Mini-Mental State Examination score 1-12; modified Hachinski Ischemic Score ≤ 6 ; Functional Assessment Staging ≥ 6) were enrolled in this study in Japan. A total of 325 patients were randomized to donepezil 5 mg/day (n = 110), donepezil 10 mg/day (n = 103) or placebo (n = 112). Primary outcome measures were change from baseline to endpoint in the Severe Impairment Battery (SIB) and Clinician's Interview-Based Impression of Change-plus caregiver input (CIBIC-plus) at the endpoint visit. RESULTS: Donepezil 5 mg/day and 10 mg/day were significantly superior to placebo on the SIB, with a least-squares mean treatment difference of 6.7 and 9.0, respectively ($p < 0.001$ compared with placebo). CIBIC-plus analyses showed significant differences in favor of donepezil 10 mg/day over placebo at endpoint ($p = 0.003$). A statistically significant dose-response relationship was demonstrated with the SIB and CIBIC-plus. Donepezil was well tolerated. CONCLUSION: This study confirmed the effectiveness of donepezil 10 mg/day in patients with severe AD and demonstrated a significant dose-response relationship. Donepezil at dosages of both 5 mg/day and 10 mg/day is safe and well tolerated in Japanese patients with severe AD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/735/CN-00638735/frame.html>

Record #293 of 370



ID: CN-00724622

AU: Essence AD

TI: A double blind, placebo controlled trial of aromatherapy using melissa/lavender compared to aricept for the treatment of significant agitation in people with severe dementia

YR: 2008

CC: SR-COMP MED: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/622/CN-00724622/frame.html>

Record #294 of 370



ID: CN-00667916

AU: Tateno M

AU: Kobayashi S

AU: Utsumi K

AU: Morii H

AU: Fujii K

TI: Quantitative analysis of the effects of donepezil on regional cerebral blood flow in Alzheimer's disease by using an automated program, 3DSRT.

SO: Neuroradiology

YR: 2008

VL: 50

NO: 8

PG: 723-7

PM: PUBMED 18483726

PT: Controlled Clinical Trial; Journal Article

KY: Alzheimer Disease [drug therapy] [physiopathology] [radionuclide imaging];Cerebrovascular Circulation [drug effects];Cholinesterase Inhibitors [administration & dosage] [pharmacology];Dose-Response Relationship, Drug;Drug Administration Schedule;Follow-Up Studies;Image Processing, Computer-Assisted;Indans [administration & dosage] [pharmacology];Piperidines [administration & dosage] [pharmacology];Tomography, Emission-Computed, Single-Photon;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1007/s00234-008-0401-y

AB: INTRODUCTION: Donepezil, an acetylcholinesterase inhibitor, has been reported to have an effect that improves cerebral blood flow (CBF) alongside its primary effect on memory function. The aim of this study was to investigate the effects of long-term, low-dose donepezil therapy on blood perfusion in Alzheimer's disease (AD) by using a fully automated regional CBF

quantification program named 3DSRT. MATERIALS AND METHODS: Fifteen subjects with mild to moderate AD according to NINCDS/ADRDA criteria underwent 99mTc-ethylcysteinate dimer (ECD) brain perfusion single photon emission computed tomography (SPECT) twice with an interval of 55.1 +/- 11.0 weeks. The dose of donepezil was fixed at 5 mg/day following the induction period (3 mg/day) of 2 weeks. Clinical efficacy of donepezil was assessed by using the Mini-Mental State Examination (MMSE). The results of SPECT imaging under exactly identical conditions were analyzed by 3DSRT, which enables us to perform a very objective assessment. RESULTS: Despite a decrease of the MMSE score from 20.9 +/- 4.7 to 18.7 +/- 5.7, CBF was increased in almost all cerebral areas except the left temporal segment. The increase was statistically significant in the left callosomarginal, right central, and bilateral pericallosal and lenticular nucleus segments. CONCLUSION: Thus far, no direct cerebrovascular effects have been reported for donepezil. We hypothesize that these CBF-promoting effects of donepezil might be related to increased neuronal activity and enhanced connection of neurons.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/916/CN-00667916/frame.html>

Record #295 of 370



ID: CN-00629346

AU: Moraes W

AU: Poyares D

AU: Sukys-Claudino L

AU: Guilleminault C

AU: Tufik S

TI: Donepezil improves obstructive sleep apnea in Alzheimer disease: a double-blind, placebo-controlled study.

SO: Chest

YR: 2008

VL: 133

NO: 3

PG: 677-83

PM: PUBMED 18198262

PT: Comparative Study; Journal Article; Multicenter Study; Randomized Controlled Trial


KY: Alzheimer Disease [complications] [drug therapy] [psychology]; Double-Blind Method; Follow-Up Studies; Indans [therapeutic use]; Nootropic Agents [therapeutic use]; Piperidines [therapeutic use]; Polysomnography; Psychometrics [methods]; Sleep Apnea, Obstructive [complications] [drug therapy] [physiopathology]; Sleep, REM [physiology]; Treatment Outcome; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

CC: SR-AIRWAYS; SR-DEMENTIA

DOI: 10.1378/chest.07-1446

AB: BACKGROUND: There is an association between Alzheimer disease and sleep-disordered breathing. Donepezil is the drug most frequently used to treat cognitive symptoms in Alzheimer disease. This study evaluates the effects of donepezil on obstructive sleep apnea in patients with Alzheimer disease. METHODS: Randomized, double-blind, placebo-controlled design. Twenty-three patients with mild-to-moderate Alzheimer disease and apnea-hypopnea index (AHI) > 5/h were allocated to two groups: donepezil treated (n = 11) and placebo treated (n = 12). Polysomnography and cognitive evaluation using Alzheimer disease assessment scale-cognitive (ADAS-cog) subscale were performed at baseline and after 3 months. Cognitive and sleep data were analyzed using analysis of variance. RESULTS: AHI and oxygen saturation improved significantly after donepezil treatment compared to baseline and placebo (p < 0.05). Rapid eye movement (REM) sleep duration increased after donepezil treatment (p < 0.05). ADAS-cog scores improved after donepezil treatment, although they did not correlate with REM sleep increase and sleep apnea improvement (p < 0.01). CONCLUSIONS: Donepezil treatment improved AHI and oxygen saturation in patients with Alzheimer disease. Treatment also increased REM sleep duration and reduced ADAS-cog scores. Trial registration: ClinicalTrials.gov Identifier: NCT00480870.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/346/CN-00629346/frame.html>

Record #296 of 370 

ID: CN-00637991

AU: Dichgans M

AU: Markus HS

AU: Salloway S

AU: Verkkoniemi A

AU: Moline M

AU: Wang Q

AU: Posner H

AU: Chabriat HS

TI: Donepezil in patients with subcortical vascular cognitive impairment: a randomised double-blind trial in CADASIL.

SO: Lancet neurology

YR: 2008

VL: 7

NO: 4

PG: 310-8

PM: PUBMED 18296124

PT: Clinical Trial; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: CADASIL [complications];Cognition Disorders [drug therapy] [etiology];Confidence Intervals;Double-Blind Method;Indans [therapeutic use];International Cooperation;Mental Status Schedule;Neuropsychological Tests;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Problem Solving [drug effects];Adult[checkword];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1016/S1474-4422(08)70046-2

AB: BACKGROUND: Cholinergic deficits might contribute to vascular cognitive impairment. Trials of cholinesterase inhibitors in patients with vascular dementia are difficult because of heterogeneous disease mechanisms and overlap between vascular and Alzheimer's disease (AD) pathology in the age-group recruited. Cerebral autosomal dominant arteriopathy with subcortical infarcts and leucoencephalopathy (CADASIL) is a genetic form of subcortical ischaemic vascular dementia. It represents a homogeneous disease process, and because of CADASIL's early onset, comorbid AD pathology is rare. We did a multicentre, 18-week, placebo-controlled, double-blind, randomised parallel-group trial to determine whether the cholinesterase inhibitor donepezil improves cognition in patients with CADASIL. METHODS: 168 patients with CADASIL (mean age 54.8 years) were assigned to 10 mg donepezil per day (n=86) or placebo (n=82) by a computer-generated randomisation protocol. Inclusion criteria included a mini-mental state examination (MMSE) score of 10-27 or a trail making test (TMT) B time score at least 1.5 SD below the mean, after adjustment for age and education. The

primary endpoint was change from baseline in the score on the vascular AD assessment scale cognitive subscale (V-ADAS-cog) at 18 weeks. Secondary endpoints included scores on the ADAS-cog, MMSE, TMT A time and B time, Stroop, executive interview-25 (EXIT25), CLOX, disability assessment for dementia, and sum of boxes of the clinical dementia rating scale. Analysis was done by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00103948. FINDINGS: 161 patients were analysed. There was no significant difference between donepezil (n=84) and placebo (n=77) in the primary endpoint. The least-squares mean change from baseline score was -0.81 (SE 0.59) in the placebo group and -0.85 (SE 0.57) in the donepezil group (p=0.956). There was a significant treatment effect favouring donepezil on the following secondary outcomes: TMT B time (p=0.023), TMT A time (p=0.015), and EXIT25 (p=0.022). Ten donepezil-treated patients discontinued treatment due to adverse events compared to seven placebo-treated patients. INTERPRETATION: Donepezil had no effect on the primary endpoint, the V-ADAS-cog score in CADASIL patients with cognitive impairment. Improvements were noted on several measures of executive function, but the clinical relevance of these findings is not clear. Our findings may have implications for future trial design in subcortical vascular cognitive impairment.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/991/CN-00637991/frame.html>

Record #297 of 370



ID: CN-00724656

AU: Anon

TI: [Public title] Pharmacokinetic interaction between AZD3480 and donepezil; [Scientific title] A double-blind, randomised, cross-over, placebo-controlled study of repeated oral doses of AZD3480 and a single dose of donepezil to evaluate the pharmacokinetic interaction between AZD3480 and donepezil in healthy extensive and poor metabolisers of CYP2D6

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2008

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/656/CN-00724656/frame.html>

Record #298 of 370



ID: CN-00682188

AU: Akhondzadeh S

AU: Gerami M

AU: Noroozian M

AU: Karamghadiri N

AU: Ghoreishi A

AU: Abbasi SH

AU: Rezazadeh SA

TI: A 12-week, double-blind, placebo-controlled trial of donepezil adjunctive treatment to risperidone in chronic and stable schizophrenia.

SO: Progress in neuro-psychopharmacology & biological psychiatry

YR: 2008

VL: 32

NO: 8

PG: 1810-5

PM: PUBMED 18727948

PT: Clinical Trial; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Antipsychotic Agents [therapeutic use];Chronic Disease [drug therapy];Double-Blind Method;Indans [pharmacology] [therapeutic use];Mental Status Schedule;Neuropsychological Tests;Nootropic Agents [pharmacology] [therapeutic use];Piperidines [pharmacology] [therapeutic use];Prospective Studies;Risperidone [therapeutic use];Schizophrenia [drug therapy] [physiopathology];Treatment Outcome;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Young Adult[checkword]

DOI: 10.1016/j.pnpbp.2008.08.001

AB: There is considerable incentive to develop new treatment strategies that effectively target cognitive deficits in schizophrenia. One of the theoretically promising novel treatment candidates is acetylcholinesterase inhibitors that increase the synaptic levels of cholinergic, nicotinic, and muscarinic receptor activity. The purpose of this study was to assess the efficacy of donepezil as an adjuvant agent in the treatment of chronic schizophrenia in particular for cognitive impairments. This investigation was a 12-week, double-blind study of parallel groups of patients with stable chronic schizophrenia. Thirty patients were recruited from inpatient

and outpatient departments, age ranging from 22 to 44 years. All participants met DSM-IV-TR. diagnostic criteria for schizophrenia. To be eligible, patients were required to have been treated with a stable dose of risperidone as their primary antipsychotic treatment for a minimum period of 8 weeks. The subjects were randomized to receive donepezil (10 mg/day) or placebo, in addition to risperidone (4-6 mg/day). Clinical psychopathology was assessed with Positive and Negative Syndrome Scale (PANSS). Cognition was measured by a cognitive battery. Patients were assessed by a psychiatrist at baseline and after 8, and 12 weeks after the medication started. The PANSS scores and cognitive performance were used as the outcome measures. The donepezil group had significantly greater improvement in the negative symptoms over the 12-week trial. There were no differences between the donepezil and placebo groups on any neurocognitive assessments at endpoint (week 12). The present study indicates donepezil as a potential adjunctive treatment strategy for negative symptoms of chronic schizophrenia.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/188/CN-00682188/frame.html>

Record #299 of 370



ID: CN-00958943

AU: Rozzini L

AU: Chilovi V

AU: Bertoletti E

AU: Ghianda D

AU: Conti M

AU: Trabucchi M

AU: Padovani A

TI: Serum albumin level interferes with the effect of Donepezil in Alzheimer's disease.

SO: Aging clinical and experimental research

YR: 2008

VL: 20

NO: 6

PG: 509-12

XR: EMBASE 2009090050

PT: Journal: Article

KY: aged // albumin blood level // *Alzheimer disease/dt [Drug Therapy] // Alzheimer disease Assessment Scale Cog score // article // biological monitoring // clinical trial // cognitive defect/dt [Drug Therapy] // comorbidity // controlled clinical trial // controlled study // drug distribution // drug dose comparison // drug dose increase // drug efficacy // drug response // female // functional assessment // general condition improvement // human // major clinical study // male // Mini Mental State Examination // outpatient // psychological assessment // scoring system // *albumin/ec [Endogenous Compound] // cholinesterase inhibitor/dt [Drug Therapy] // *donepezil/ct [Clinical Trial] // *donepezil/do [Drug Dose] // *donepezil/dt [Drug Therapy] // *donepezil/pk [Pharmacokinetics] // rivastigmine/do [Drug Dose] // rivastigmine/dt [Drug Therapy]

AB: Background and aims: The most successful therapeutic approaches to Alzheimer's disease (AD) have involved acetylcholinesterase inhibitors (ChEIs). In view of the different response rates to ChEIs therapy, it is important to identify the pharmacokinetic and pharmacodynamic mechanisms which may interfere with this effect. The aim of the study is to evaluate the efficacy on cognition of donepezil, a cholinesterase inhibitor, in a sample of mild to moderate AD patients with various serum albumin levels, a condition modifying drug distribution. Methods: Ninety-eight Alzheimer patients treated with donepezil were analyzed in an outpatient clinic between January 2003 and January 2005. At study entry, participants underwent multidimensional assessment evaluating cognitive, functional and psychobehavioral domains. All concomitant illnesses and treatments were recorded. Patients were grouped in three categories (with low, medium and high albumin levels). Results: The total sample of patients showed cognitive improvement from baseline of the ADAS Cog score at three months (ADAS Cog mean change -1.4 ± 5.4 ; $p=0.01$), cognitive stabilization at nine months (ADAS Cog mean change 0.03 ± 6.7 ; $p=ns$), and not statistically significant worsening at fifteen months (ADAS Cog mean change 0.9 ± 7.3 ; $p=ns$). The low serum albumin level group was associated with a greater response to donepezil. In fact, cognition, evaluated by the ADAS Cog mean change from baseline, improved during the first 15 months of treatment in the low serum albumin level group, but worsened in the two higher groups. Conclusion: Our preliminary data suggest that serum albumin level should be monitored to evaluate the clinical efficacy of ChEIs therapy. 2008, Editrice Kurtis.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/943/CN-00958943/frame.html>

Record #300 of 370



ID: CN-00628338

AU: Leyhe T

AU: Stransky E

AU: Eschweiler GW

AU: Buchkremer G

AU: Laske C

TI: Increase of BDNF serum concentration during donepezil treatment of patients with early Alzheimer's disease.

SO: European archives of psychiatry and clinical neuroscience

YR: 2008

VL: 258

NO: 2

PG: 124-8

PM: PUBMED 17990049

PT: Controlled Clinical Trial; Journal Article

KY: Alzheimer Disease [blood] [drug therapy];Brain-Derived Neurotrophic Factor [blood] [drug effects];Case-Control Studies;Cholinesterase Inhibitors [therapeutic use];Follow-Up Studies;Indans [therapeutic use];Matched-Pair Analysis;Piperidines [therapeutic use];Up-Regulation;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1007/s00406-007-0764-9

AB: Alzheimer's disease (AD) can be treated with inhibitors of the enzyme acetylcholinesterase (AChE). Recent pre-clinical and clinical studies gave evidence that AChE-inhibitors have neuroprotective effects and thereby a disease-modifying potential. The mechanism of this action is still discussed. In an animal model oral administration of an AChE-inhibitor lead to an increase of brain derived neurotrophic factor (BDNF) in hippocampus and cortex. Recent studies have found a decrease of BDNF in the serum and brain of AD patients with potentially consecutive lack of neurotrophic support and contribution to progressive neurodegeneration. BDNF serum concentrations were assessed by ELISA in 19 AD patients and 20 age-matched healthy controls at baseline and in the AD patients after 15 months of treatment with donepezil 10 mg per day (one patient received just 5 mg). Before treatment with donepezil we found in AD significantly decreased BDNF serum concentrations (19.2 ± 3.7 ng/ml) as compared to healthy controls (23.2 ± 6.0 ng/ml, $P = 0.015$). After 15 months of treatment the BDNF serum concentration increased significantly in the AD patients (23.6 ± 7.0 ng/ml, $P = 0.001$) showing no more difference to the healthy controls ($P = 0.882$). The results of the present study confirm data of prior investigations that a down-regulation of BDNF in serum and brain of AD patients seems to begin with the first clinical symptoms and to be persistent. A

treatment with the AChE-inhibitor donepezil is accompanied with an increase of BDNF serum concentration in AD patients reaching the level of healthy controls. Thus, up-regulation of BDNF might be part of a neuroprotective effect of AChE-inhibitors. The molecular mechanism of this potentially disease-modifying mechanism of action of donepezil should be clarified.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/338/CN-00628338/frame.html>

Record #301 of 370



ID: CN-00649771

AU: Jones RW

AU: Kivipelto M

AU: Feldman H

AU: Sparks L

AU: Doody R

AU: Waters DD

AU: Hey-Hadavi J

AU: Breazna A

AU: Schindler RJ

AU: Ramos H

TI: The Atorvastatin/Donepezil in Alzheimer's Disease Study (LEADe): design and baseline characteristics.

SO: Alzheimer's & dementia

YR: 2008

VL: 4

NO: 2

PG: 145-53

PM: PUBMED 18631958

XR: EMBASE 2008124762

PT: Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Alzheimer Disease [blood] [drug therapy];Anticholesteremic Agents [administration & dosage];Cholinesterase Inhibitors [administration & dosage];Drug Therapy, Combination;Heptanoic Acids [administration & dosage];Indans [administration & dosage];Lipids [blood];Piperidines [administration & dosage];Pyrroles [administration & dosage];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1016/j.jalz.2008.02.001

AB: BACKGROUND: Growing evidence suggests that elevated cholesterol levels in mid-life are associated with increased risk of developing Alzheimer's disease (AD), and that statins might have a protective effect against AD and dementia. The Lipitor's Effect in Alzheimer's Dementia (LEADe) study tests the hypothesis that a statin (atorvastatin 80 mg daily) will provide a benefit on the course of mild to moderate AD in patients receiving background therapy of a cholinesterase inhibitor (donepezil 10 mg daily). METHODS: This is an international, multicenter, double-blind, randomized, parallel-group study with a double-blind randomized withdrawal phase of patients with mild to moderate AD (Mini-Mental State Examination [MMSE] score, 13 to 25). Inclusion criteria included age 50 to 90 years, receiving donepezil 10 mg for at least 3 months before randomization, and low-density lipoprotein cholesterol levels (LDL-C) 2.5 to 3.5 mmol/L (95 to 195 mg/dL). Co-primary end points are changes in AD Assessment Scale-cognitive subscale (ADAS-cog) and AD Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC) scale scores. A confirmatory end point is rate of change in whole brain and hippocampal volumes in patients who enrolled in the magnetic resonance imaging substudy. RESULTS: Enrollment of 641 subjects is complete. The baseline mean data are age 74 +/- 8 years, 53% women, MMSE 22 +/- 3, ADAS-cog 23 +/- 10, AD Functional Assessment and Change Scale (ADFACS) 13 +/- 9, Neuropsychiatric Inventory (NPI) 10 +/- 11, and Clinical Dementia Rating-Sum of Boxes (CDR-SB) 6 +/- 3. Mean prior donepezil treatment was 409 +/- 407 days. Mean baseline lipid levels are total cholesterol 5.8 +/- 0.8 mmol/L (224 +/- 33 mg/dL), LDL-C 3.7 +/- 0.7 mmol/L (143 +/- 26 mg/dL), triglycerides 1.5 +/- 0.7 mmol/L (132 +/- 64 mg/dL), and high-density lipoprotein cholesterol 1.6 +/- 0.5 mmol/L (64 +/- 18 mg/dL). CONCLUSIONS: LEADe will report in 2008 and is expected to provide a more definitive evaluation of the potential for statins in the treatment of people with AD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/771/CN-00649771/frame.html>

Record #302 of 370



ID: CN-00640507

AU: ErKent U

AU: Koytchev R

TI: The use of truncated area under the curves in the bioequivalence evaluation of long half-life drugs. Studies with donepezil and memantine.

SO: Arzneimittel-Forschung

YR: 2008

VL: 58

NO: 5

PG: 255-8

PM: PUBMED 18589560


PT: Journal Article; Randomized Controlled Trial

KY: Adolescent; Algorithms; Area Under Curve; Cross-Over Studies; Excitatory Amino Acid Antagonists [administration & dosage] [pharmacokinetics]; Half-Life; Indans [administration & dosage] [pharmacokinetics]; Linear Models; Memantine [administration & dosage] [pharmacokinetics]; Models, Statistical; Nootropic Agents [administration & dosage] [pharmacokinetics]; Piperidines [administration & dosage] [pharmacokinetics]; Tablets, Enteric-Coated; Therapeutic Equivalency; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

DOI: 10.1055/s-0031-1296502

AB: The bioequivalence of long terminal half-life drugs, donepezil (CAS 120014-06-4) 10 mg and memantine (CAS 19982-08-2) 10 mg, was evaluated by comparing the results obtained for the total areas under the concentration time curves (AUC(0-inf)) with those for partial AUCs: AUC(0-216h), AUC(0-72h) and AUC(0-48h). Pharmacokinetic endpoints were determined by standard formulas from the concentration-time courses of the parent compounds donepezil and memantine. The results of the bioequivalence assessment based on the 90% confidence intervals calculated by means of ANOVA for logarithmically transformed values (ANOVA log) led to exactly the same decision irrespective of the type of AUC used. The 90% confidence intervals for all types of AUCs were practically identical within each product. These results prove that truncated AUCs, e.g. AUC(0-72h) or even AUC(0-48h), can be adequately used in assessing the relative bioavailability of long terminal half-life drugs. The findings suggest that even for drugs with half-lives between 24 and 60 h and thus shorter than those of donepezil and memantine an AUC truncated to 48 h post dose can be successfully used for the assessment of bioequivalence as this sample collection time ensures a proper comparison of the absorption process as recommended in the CPMP Note for Guidance on the Investigation of Bioavailability and Bioequivalence.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/507/CN-00640507/frame.html>

Record #303 of 370 

ID: CN-00714120

AU: Anon


TI: [Public title] Safety and tolerability of dimebon in patients on memantine, and memantine plus donepezil; [Scientific title] Safety and tolerability of dimebon in patients on memantine, and memantine plus donepezil

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2008

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/120/CN-00714120/frame.html>

Record #304 of 370 

ID: CN-00741744

AU: Cre?u O

AU: Szalontay AS

AU: Chiri?? R

AU: Chiri?? V

TI: [Effect of memantine treatment on patients with moderate-to-severe Alzheimer's disease treated with donepezil]. [Romanian]

SO: Revista medico-chirurgical?? a Societ????ii de Medici ??i Naturali??ti din Ia??i

YR: 2008

VL: 112

NO: 3

PG: 641-5

PM: PUBMED 20201245

PT: Comparative Study; English Abstract; Journal Article; Randomized Controlled Trial

KY: Aggression [drug effects];Alzheimer Disease [diagnosis] [drug therapy];Cholinesterase Inhibitors [therapeutic use];Cognition [drug effects];Dopamine Agents [therapeutic use];Drug Therapy, Combination;Indans [therapeutic use];Memantine [therapeutic use];Neuropsychological Tests;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Prospective Studies;Severity of Illness Index;Treatment Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA

AB: OBJECTIVE: Investigating the behavioral and cognitive effect of memantine in moderate to severe patients with Alzheimer's disease receiving donepezil. MATERIAL AND METHOD: 43 patients were enrolled in this prospective, randomized, parallel group study. There were no significant imbalances between the treatment groups in demographic and baseline clinical characteristics. Cognitive and global measures were collected at baseline and at the end of weeks 4, 8, 12 and 24. Behavioral measures were collected at baseline, at the end of week 12 and at week 24. RESULTS: Memantine--treated patients showed significantly less deterioration in their functionality. Of patients who exhibited agitation/aggression at baseline, those treated with memantine and donepezil showed significant reduction of symptoms compared with donepezil--treated patients. CONCLUSIONS: Treatment with memantine was well tolerated and reduced agitation/aggression, irritability, and appetite eating disturbances in patients who were agitated at baseline and delayed its emergence in those who were free of agitation at baseline.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/744/CN-00741744/frame.html>

Record #305 of 370



ID: CN-00648923

AU: FitzGerald DB

AU: Crucian GP

AU: Mielke JB

AU: Shenal BV

AU: Burks D

AU: Womack KB

AU: Ghacibeh G

AU: Drago V

AU: Foster PS

AU: Valenstein E

AU: Heilman KM

TI: Effects of donepezil on verbal memory after semantic processing in healthy older adults.

SO: Cognitive and behavioral neurology

YR: 2008

VL: 21

NO: 2

PG: 57-64

PM: PUBMED 18541979

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't; Research Support, U.S. Gov't, Non-P.H.S.

KY: Alzheimer Disease [drug therapy] [psychology];Attention [drug effects];Cholinesterase Inhibitors [therapeutic use];Comprehension;Dose-Response Relationship, Drug;Double-Blind Method;Indans [therapeutic use];Memory, Short-Term [drug effects];Mental Recall [drug effects];Neuropsychological Tests;Nootropic Agents [therapeutic use];Pattern Recognition, Visual;Piperidines [therapeutic use];Retention (Psychology) [drug effects];Semantics;Serial Learning [drug effects];Verbal Learning [drug effects];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-DEMENTIA

DOI: 10.1097/WNN.0b013e3181799df1

AB: OBJECTIVE: To learn if acetylcholinesterase inhibitors alter verbal recall by improving semantic encoding in a double-blind randomized placebo-controlled trial. BACKGROUND: Cholinergic supplementation has been shown to improve delayed recall in adults with Alzheimer disease. With functional magnetic resonance imaging, elderly adults, when compared with younger participants, have reduced cortical activation with semantic processing. There have been no studies investigating the effects of cholinergic supplementation on semantic encoding in healthy elderly adults. METHOD: Twenty elderly participants (mean age 71.5, SD+/-5.2) were recruited. All underwent memory testing before and after receiving donepezil (5 mg, n=11 or 10 mg, n=1) or placebo (n=8) for 6 weeks. Memory was tested using a Levels of Processing task, where a series of words are presented

serially. Subjects were either asked to count consonants in a word (superficially process) or decide if the word was "pleasant" or "unpleasant" (semantically process). RESULTS: After 6 weeks of donepezil or placebo treatment, immediate and delayed recall of superficially and semantically processed words was compared with baseline performance. Immediate and delayed recall of superficially processed words did not show significant changes in either treatment group. With semantic processing, both immediate and delayed recall performance improved in the donepezil group. CONCLUSIONS: Our results suggest that when using semantic encoding, older normal subjects may be aided by anticholinesterase treatment. However, this treatment does not improve recall of superficially encoded words.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/923/CN-00648923/frame.html>

Record #306 of 370



ID: CN-00639444

AU: Kanetaka H

AU: Hanyu H

AU: Hirao K

AU: Shimizu S

AU: Sato T

AU: Akai T

AU: Iwamoto T

AU: Koizumi K

TI: Prediction of response to donepezil in Alzheimer's disease: combined MRI analysis of the substantia innominata and SPECT measurement of cerebral perfusion.

SO: Nuclear medicine communications

YR: 2008

VL: 29

NO: 6

PG: 568-73

PM: PUBMED 18458605

PT: Controlled Clinical Trial; Journal Article

KY: Alzheimer Disease [diagnosis] [drug therapy];Brain [blood supply] [radionuclide imaging];Cerebrovascular Circulation [drug effects];Indans [administration & dosage];Nootropic Agents [administration & dosage];Outcome Assessment (Health Care) [methods];Piperidines [administration & dosage];Reproducibility of Results;Sensitivity and Specificity;Substantia Innominata [drug effects] [pathology];Subtraction Technique;Tomography, Emission-Computed, Single-Photon [methods];Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1097/MNM.0b013e3282f5e5f4

AB: OBJECTIVE: We performed combined studies of magnetic resonance imaging (MRI) analysis of the substantia innominata and single photon emission CT (SPECT) measurement of cerebral perfusion with the goal of predicting which patients with Alzheimer's disease are most likely to respond to donepezil treatment. METHODS: Ninety-one patients treated with donepezil were divided into responders and non-responders on the basis of changes in their MMSE scores from baseline to study endpoint. The thickness of the substantia innominata was measured on the coronal T2-weighted MRI through the anterior commissure. SPECT data were analysed using three-dimensional stereotactic surface projections. RESULTS: Responders had significantly greater atrophy of the substantia innominata, but less prominent frontal hypoperfusion than non-responders. Receiver operating characteristic analysis revealed that combined MRI and SPECT examination showed an overall discrimination rate of 70% between responders and non-responders. DISCUSSION: Our results suggest that responder patients have more severe damage in the cholinergic system and/or less prominent frontal cortical dysfunction. Combined MRI analysis of the substantia innominata and SPECT measurement of frontal perfusion at baseline may help to predict response to donepezil treatment in patients with Alzheimer's disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/444/CN-00639444/frame.html>

Record #307 of 370



ID: CN-00714077

AU: Anon


TI: A study of prx-03140 in subjects with Alzheimer's disease receiving a stable dose of donepezil or phase 2 double-blind study of prx-03140 in subjects with Alzheimer's disease receiving a stable dose of donepezil

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2008

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/077/CN-00714077/frame.html>

Record #308 of 370 

ID: CN-00647055

AU: Jack CR

AU: Petersen RC

AU: Grundman M

AU: Jin S

AU: Gamst A

AU: Ward CP

AU: Sencakova D

AU: Doody RS

AU: Thal LJ

TI: Longitudinal MRI findings from the vitamin E and donepezil treatment study for MCI.

SO: Neurobiology of aging

YR: 2008

VL: 29

NO: 9

PG: 1285-95

PM: PUBMED 17452062

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Antioxidants [administration & dosage];Atrophy [drug therapy] [epidemiology] [pathology];Cholinesterase Inhibitors [administration & dosage];Cognition Disorders [drug therapy] [epidemiology] [pathology];Hippocampus [drug effects] [pathology];Incidence;Indans [administration & dosage];Longitudinal Studies;Piperidines [administration & dosage];Treatment Outcome;United States [epidemiology];Vitamin E [administration &

dosage];Aged[checkword];Aged, 80 and
over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle
Aged[checkword]

DOI: 10.1016/j.neurobiolaging.2007.03.004

AB: The vitamin E and donepezil trial for the treatment of amnesic mild cognitive impairment (MCI) was conducted at 69 centers in North America; 24 centers participated in an MRI sub study. The objective of this study was to evaluate the effect of treatment on MRI atrophy rates; and validate rate measures from serial MRI as indicators of disease progression in multi center therapeutic trials for MCI. Annual percent change (APC) from baseline to follow-up was measured for hippocampus, entorhinal cortex, whole brain, and ventricle in the 131 subjects who remained in the treatment study and completed technically satisfactory baseline and follow-up scans. Although a non-significant trend toward slowing of hippocampal atrophy rates was seen in APOE is an element of 4 carriers treated with donepezil; no treatment effect was confirmed for any MRI measure in either treatment group. For each of the four brain atrophy rate measures, APCs were greater in subjects who converted to AD than non-converters, and were greater in APOE is an element of 4 carriers than non-carriers. MRI APCs and changes in cognitive test performance were uniformly correlated in the expected direction (all $p < 0.000$). Results of this study support the feasibility of using MRI as an outcome measure of disease progression in multi center therapeutic trials for MCI.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/055/CN-00647055/frame.html>

Record #309 of 370



ID: CN-00630627

AU: Galvin JE

AU: Cornblatt B

AU: Newhouse P

AU: Ancoli-Israel S

AU: Wesnes K

AU: Williamson D

AU: Zhu Y

AU: Sorra K

AU: Amatniek J

TI: Effects of galantamine on measures of attention: results from 2 clinical trials in Alzheimer disease patients with comparisons to donepezil.

SO: Alzheimer disease and associated disorders

YR: 2008

VL: 22

NO: 1

PG: 30-8

PM: PUBMED 18317244

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy];Attention [drug effects];Cholinesterase Inhibitors [therapeutic use];Double-Blind Method;Galantamine [therapeutic use];Indans [therapeutic use];Neuropsychological Tests;Piperidines [therapeutic use];Single-Blind Method;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1097/WAD.0b013e3181630b81

AB: Deficits in attention are present early in the course of Alzheimer disease (AD). Acetylcholine receptors are appealing molecular targets for intervention as cholinergic pathways are involved in the neurobiology of attention. For this reason, measures of attention were included in 2 independent, multicenter, randomized, parallel, controlled trials in subjects with AD comparing the effects of galantamine, an acetylcholinesterase inhibitor and postulated nicotinic receptor modulator, and donepezil, an acetylcholinesterase inhibitor. The attention battery of the Cognitive Drug Research computerized assessment system was used in both trials. Small magnitude, positive signals were observed for simple and choice reaction times for both compounds. Attention task performance tended to improve early for galantamine-treated subjects. A consistent temporal pattern of improvement was not observed in donepezil-treated subjects. Quantitative findings appeared more pronounced in subjects with moderate AD. Galantamine's proposed action as a nicotinic receptor modulator may bear on these findings. Improved attention may have positive effects on cognitive and functional outcomes for AD patients, although this hypothesis requires further study and validation.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/627/CN-00630627/frame.html>

Record #310 of 370



ID: CN-00648766

AU: Thomas E

AU: Snyder PJ

AU: Pietrzak RH

AU: Jackson CE

AU: Bednar M

AU: Maruff P

TI: Specific impairments in visuospatial working and short-term memory following low-dose scopolamine challenge in healthy older adults.

SO: Neuropsychologia

YR: 2008

VL: 46

NO: 10

PG: 2476-84

PM: PUBMED 18514746

PT: Journal Article; Randomized Controlled Trial

KY: Analysis of Variance;Cholinesterase Inhibitors [therapeutic use];Dose-Response Relationship, Drug;Double-Blind Method;Geriatric Assessment;Indans [therapeutic use];Linear Models;Maze Learning [drug effects];Memory Disorders [chemically induced] [drug therapy];Memory, Short-Term [drug effects];Piperidines [therapeutic use];Scopolamine Hydrobromide [adverse effects];Spatial Behavior [drug effects] [physiology];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-DEMENTIA

DOI: 10.1016/j.neuropsychologia.2008.04.010

AB: Scopolamine-induced deficits in cognitive and motor processes have been widely demonstrated in animals and humans, although the role of acetylcholine in working memory is not as well understood. This study examined the role of acetylcholine neurotransmission in visuospatial short term and working memory using the Groton Maze Learning Test (GMLT). The GMLT is a computerized hidden maze learning test that yields measures of component cognitive processes such as spatial memory, working memory, and visuomotor function, as well as their integration in trial-and-error problem solving. Healthy older adults were

administered scopolamine (0.3 mg subcutaneous), the acetylcholinesterase inhibitor donepezil (5 mg oral), scopolamine with donepezil, or placebo. Compared to placebo, low-dose scopolamine led to performance deficits on all measures of the GMLT. The greatest scopolamine-induced deficits were observed in errors reflecting working memory processes (e.g., perseverative errors $d=-2.98$, and rule-break errors $d=-2.49$) and these impairments remained robust when statistical models accounted for scopolamine-related slowing in visuomotor speed. Co-administration of donepezil partially ameliorated scopolamine-related impairments and this effect was greatest for measures of working memory than short-term memory. By itself, donepezil was associated with a small improvement in visuomotor function. These results suggest that scopolamine disrupts processes required for rule maintenance and performance monitoring, in combination with visuomotor slowing and sequential location learning.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/766/CN-00648766/frame.html>

Record #311 of 370



ID: CN-00629694

AU: Lyle S

AU: Grizzell M

AU: Willmott S

AU: Benbow S

AU: Clark M

AU: Jolley D

TI: Treatment of a whole population sample of Alzheimer's disease with donepezil over a 4-year period: lessons learned.

SO: Dementia and geriatric cognitive disorders

YR: 2008

VL: 25

NO: 3

PG: 226-31

PM: PUBMED 18230972

PT: Journal Article; Randomized Controlled Trial

KY: Alzheimer Disease [diagnosis] [drug therapy];Cholinesterase Inhibitors [therapeutic use];Cognition Disorders [diagnosis];Cohort Studies;Double-Blind Method;Indans [therapeutic use];Neuropsychological Tests;Piperidines [therapeutic use];Severity of Illness Index;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1159/000114450

AB: BACKGROUND: In the UK it is recommended that acetylcholinesterase inhibitors be restricted to patients with moderate Alzheimer's disease, and progress monitored within specialist clinics. Objective: To describe a cohort of patients with Alzheimer's disease from a whole city population treated with donepezil, and to analyse outcomes over 4 years. METHODS: Historical cohort design: 88 patients recruited 1997-1998, assessed at baseline with 4-year follow-up, using an agreed protocol and validated measures: survival, retention in treatment, cognition, non-cognitive symptoms, weight change, carer stress. RESULTS: 64.7% remained on treatment beyond 6 months, 57.9% beyond 1 year and 12.5% beyond 4 years. 56% remained alive at 4 years - almost twice the number predicted. Mean MMSE score amongst patients in treatment did not deteriorate over 4 years. Survival, retention in treatment, maintenance/improvement of cognition was greater with high baseline MMSE. Non-cognitive symptoms, carer stress and weight change remained low throughout. CONCLUSIONS: A minority of people with dementia from the population (88 of potential 2,000 at outset, 11 by 4 years) received treatment. Benefits for individuals were confirmed, especially for those with mild impairment. Expenditure on medication was modest in a population context. These findings question recent guidance from the National Institute for Clinical Excellence, which would restrict therapy to patients with moderate cognitive impairment.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/694/CN-00629694/frame.html>

Record #312 of 370



ID: CN-00714049

AU: AD-DM


TI: Clinical efficacy of Donepezil on self care ability in patients with both diabetes and Alzheimer's disease

SO: UMIN CTR [<https://center.umin.ac.jp>]

YR: 2008

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/049/CN-00714049/frame.html>

Record #313 of 370 

ID: CN-00714135

AU: Anon


TI: Study az3110866, a fixed dose study of sb-742457 versus placebo when added to existing donepezil treatment in subjects with mild-to-moderate Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2008

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/135/CN-00714135/frame.html>

Record #314 of 370 

ID: CN-00687433

AU: Silver MA

AU: Shenhav A

AU: D'Esposito M

TI: Cholinergic enhancement reduces spatial spread of visual responses in human early visual cortex.

SO: Neuron

YR: 2008

VL: 60

NO: 5

PG: 904-14

PM: PUBMED 19081383

PT: Controlled Clinical Trial; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Acetylcholine [metabolism]; Brain Mapping; Cholinesterase Inhibitors [pharmacology]; Double-Blind Method; Eye Movements [drug effects] [physiology]; Image Processing, Computer-Assisted; Indans [pharmacology]; Magnetic Resonance Imaging; Oxygen [blood]; Photic Stimulation [methods]; Piperidines [pharmacology]; Psychophysics; Time Factors; Visual Cortex [blood supply] [drug effects] [physiology]; Visual Pathways [blood supply] [drug effects] [physiology]; Female[checkword]; Humans[checkword]; Male[checkword]

DOI: 10.1016/j.neuron.2008.09.038

AB: Animal studies have shown that acetylcholine decreases excitatory receptive field size and spread of excitation in early visual cortex. These effects are thought to be due to facilitation of thalamocortical synaptic transmission and/or suppression of intracortical connections. We have used functional magnetic resonance imaging (fMRI) to measure the spatial spread of responses to visual stimulation in human early visual cortex. The cholinesterase inhibitor donepezil was administered to normal healthy human subjects to increase synaptic levels of acetylcholine in the brain. Cholinergic enhancement with donepezil decreased the spatial spread of excitatory fMRI responses in visual cortex, consistent with a role of acetylcholine in reducing excitatory receptive field size of cortical neurons. Donepezil also reduced response amplitude in visual cortex, but the cholinergic effects on spatial spread were not a direct result of reduced amplitude. These findings demonstrate that acetylcholine regulates spatial integration in human visual cortex.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/433/CN-00687433/frame.html>

Record #315 of 370



ID: CN-00652413

AU: FitzGerald DB

AU: Crucian GP

AU: Mielke JB

AU: Shenal BV

AU: Burks D

AU: Womack KB

AU: Ghacibeh G

AU: Drago V

AU: Foster PS

AU: Valenstein E

AU: Heilman KM

TI: Effects of donepezil on verbal memory after semantic processing in health older adults

SO: Cognitive and Behavioral Neurology

YR: 2008

VL: 21

NO: 2

PG: 57-64

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/413/CN-00652413/frame.html>

Record #316 of 370



ID: CN-00651493

AU: Chuah LY

AU: Chee MW

TI: Cholinergic augmentation modulates visual task performance in sleep-deprived young adults.

SO: Journal of neuroscience

YR: 2008

VL: 28

NO: 44

PG: 11369-77

PM: PUBMED 18971479

PT: Comparative Study; Controlled Clinical Trial; Journal Article; Research Support, Non-U.S. Gov't

KY: Adolescent;Cholinergic Fibers [drug effects] [physiology];Cholinesterase Inhibitors [pharmacology] [therapeutic use];Cross-Over Studies;Double-Blind Method;Memory [drug effects] [physiology];Photic Stimulation [methods];Psychomotor Performance [drug effects] [physiology];Sleep Deprivation [complications] [enzymology] [prevention & control];Visual Perception [drug effects] [physiology];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1523/JNEUROSCI.4045-08.2008

AB: Using 24 h of total sleep deprivation to perturb normal cognitive function, we conducted a double-blind, placebo-controlled crossover study to evaluate the effect of the acetylcholinesterase inhibitor, donepezil, on behavioral performance and task-related brain activation in 28 healthy, young, adult volunteers. The behavioral tasks involved the parametric manipulation of visual short-term memory load and perceptual load in separate experiments indirectly evaluating attention. Sleep deprivation significantly reduced posterior cortical activation (intraparietal sulcus and extrastriate cortex) at all levels of visual memory as well as perceptual load. Donepezil modulated an individual's performance in both tasks in accordance to whether accuracy declined after sleep deprivation without treatment. Critically, there were significant correlations between donepezil-induced increases in neural activation in the posterior cortical areas and improvement in accuracy. Reduced visual short-term memory after sleep deprivation may thus originate from a decline in visual attention and/or visual processing. Cholinergic augmentation can alleviate these deficits in individuals vulnerable to the effects of sleep deprivation, but it may have neutral or negative effects on those resistant to sleep deprivation.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/493/CN-00651493/frame.html>

Record #317 of 370



ID: CN-00698721

AU: Salloway S

AU: Correia S

AU: Richardson S

TI: Key lessons learned from short-term treatment trials of cholinesterase inhibitors for amnesic MCI.

SO: International psychogeriatrics / IPA

YR: 2008

VL: 20

NO: 1

PG: 40-6

PM: PUBMED 17597552

PT: Comparative Study; Historical Article; Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Alzheimer Disease [diagnosis] [drug therapy] [psychology];Cholinesterase Inhibitors [therapeutic use];Cognition Disorders [diagnosis] [drug therapy] [psychology];Cohort Studies;Indans [therapeutic use];Memory Disorders [diagnosis] [drug therapy] [psychology];Neuropsychological Tests [statistics & numerical data];Outcome Assessment (Health Care) [statistics & numerical data];Piperidines [therapeutic use];Placebos;Psychiatric Status Rating Scales [statistics & numerical data];Psychomotor Performance;Randomized Controlled Trials as Topic [history] [statistics & numerical data];Research Design [standards];Severity of Illness Index;Treatment Outcome;United States;Aged[checkword];History, 20th Century[checkword];Humans[checkword]

CC: SR-DEMENTIA

DOI: 10.1017/S1041610207005650

AB: OBJECTIVE: This paper reviews the key lessons learned from the first published short-term, placebo-controlled trial of a cholinesterase inhibitor for treatment of mild cognitive impairment (MCI). METHODS: The study was a 24-week placebo-controlled trial designed to evaluate the efficacy and safety of donepezil HCl (donepezil) in the treatment of cognitive impairment in subjects with MCI. Primary outcome measures were the NYU Paragraphs Test and the ADCS Clinicians Global-Impression of Change in the intent-to-treat last-observation-carried-forward group. RESULTS: There was no benefit of donepezil treatment on primary outcome measures (NYU Paragraphs and ADCS CGI-C) in the ITT-LOCF group but positive findings were seen on NYU Paragraphs in the fully evaluable group and in certain secondary outcome measures across both groups. CONCLUSIONS: The results highlight the need for the use of primary cognitive and functional measures that are reliable and sensitive to change in patients with MCI. Measures of episodic memory, psychomotor speed and complex attention were most sensitive in this study. Functional rating scales are needed that measure change in individual subjects' key areas of functional deficit, which typically involve executive aspects of instrumental ADLs. Tolerability can be increased by use of flexible dosing and efficacy is likely to be enhanced by increasing the length of the trial from six to 12 months and by enriching the sample with subjects more likely to decline during the trial.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/721/CN-00698721/frame.html>



ID: CN-00638011

AU: Kadir A

AU: Andreasen N

AU: Almkvist O

AU: Wall A

AU: Forsberg A

AU: Engler H

AU: Hagman G

AU: Lärksäter M

AU: Winblad B

AU: Zetterberg H

AU: Blennow K

AU: Långström B

AU: Nordberg A

TI: Effect of phenserine treatment on brain functional activity and amyloid in Alzheimer's disease.

SO: Annals of neurology

YR: 2008

VL: 63

NO: 5

PG: 621-31

PM: PUBMED 18300284

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [metabolism] [radionuclide imaging];Amyloid [metabolism];Brain [drug effects] [metabolism] [radiation effects];Cholinesterase Inhibitors [administration & dosage];Double-Blind Method;Physostigmine [administration & dosage] [analogs & derivatives];Placebo Effect;Positron-Emission Tomography;Treatment Outcome;Aged[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-DEMENTIA

AB: OBJECTIVE: The effects of (-)-phenserine (phenserine) and placebo/donepezil treatment on regional cerebral metabolic rate for glucose (rCMRglc) and brain amyloid load were investigated by positron emission tomography in 20 patients with mild Alzheimer's disease in relation to cerebrospinal fluid (CSF) and plasma biomarkers, and cognitive function. **METHODS:** The first 3 months of the study was a randomized, double-blind, placebo-controlled phase, during which 10 patients received phenserine (30 mg/day) and 10 patients the placebo. Three to 6 months was an open-label extension phase, during which the placebo group received donepezil (5 mg/day) and the phenserine group remained on phenserine. After 6 months, all patients received phenserine treatment up to 12 months. The patients underwent positron emission tomography examinations to measure rCMRglc (8F-FDG) and amyloid load (11C-PIB) at baseline and after 3 and 6 months of the treatment. Neuropsychological and biomarker data were collected at the three times of positron emission tomography imaging. **RESULTS:** Statistically significant effects on a composite neuropsychological test score were observed in the phenserine-treated group compared with the placebo and donepezil group at 3 and 6 months, respectively. Values of rCMRglc were significantly increased in several cortical regions after 3 months of phenserine treatment, compared with baseline, and correlated positively with cognitive function and CSF beta-amyloid 40 (Abeta40). Cortical Pittsburgh Compound B retention correlated negatively with CSF Abeta40 levels and the ratio Abeta/beta-secretase-cleaved amyloid precursor protein. In CSF, Abeta40 correlated positively with the attention domain of cognition. **INTERPRETATION:** Phenserine treatment was associated with an improvement in cognition and an increase in rCMRglc.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/011/CN-00638011/frame.html>

Record #319 of 370



ID: CN-00652438

AU: Abolfazli R

AU: Ghazanshahi S

AU: Nazeman M

TI: Effects of 6 months of treatment with donepezil and rivastigmine on results of neuropsychological tests of MMSE, NPI, Clock and Bender in patients with Alzheimer's disease

SO: Acta medica Iranica

YR: 2008


VL: 46

NO: 2

PG: 99-104

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/438/CN-00652438/frame.html>

Record #320 of 370 

ID: CN-00759123

AU: Snyder PJ

AU: Maruff P

AU: Darby DG

AU: Harrison JE

TI: Improvement in cognitive function in AD and MCI following a single dose of donepezil

SO: European Journal of Neurology

YR: 2008

VL: 15


NO: Suppl 3

PG: 228, Abstract no: P2026

CC: HS-NEUROMUSC: HS-HANDSRCH

AB: Abstracts of the 12th Congress of the European Federation of Neurological Societies, Madrid, Spain, 24-25 August, 2008

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/123/CN-00759123/frame.html>

Record #321 of 370 

ID: CN-00741695

AU: Schuff N

AU: Suhy J

AU: Doody RS

AU: Goldman R

AU: Murthy AK

TI: The effects of donepezil on Alzheimer's disease progression monitored by MRI

SO: European Journal of Neurology

YR: 2008


VL: 15

NO: Suppl 3

PG: 38, Abstract no: P1024

CC: HS-NEUROMUSC: HS-HANDSRCH

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/695/CN-00741695/frame.html>

Record #322 of 370 

ID: CN-00714173

AU: Anon


TI: Donepezil and memantine in moderate to severe Alzheimer's disease

SO: ClinicalTrials.gov [www.clinicaltrials.gov]

YR: 2008

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/173/CN-00714173/frame.html>

Record #323 of 370 

ID: CN-00640025

AU: Meguro M

AU: Kasai M

AU: Akanuma K

AU: Ishii H

AU: Yamaguchi S

AU: Meguro K

TI: Comprehensive approach of donepezil and psychosocial interventions on cognitive function and quality of life for Alzheimer's disease: the Osaki-Tajiri Project.

SO: Age and ageing

YR: 2008

VL: 37

NO: 4

PG: 469-73

PM: PUBMED 18515851

PT: Journal Article; Randomized Controlled Trial

KY: Alzheimer Disease [drug therapy] [psychology];Art;Cognition Disorders [drug therapy] [psychology];Combined Modality Therapy;Indans [therapeutic use];Nootropic Agents [therapeutic use];Nursing Homes;Occupational Therapy;Piperidines [therapeutic use];Quality of Life;Social Support;Treatment Outcome;Aged[checkword];Humans[checkword]

CC: SR-BEHAVMED: SR-DEMENTIA

DOI: 10.1093/ageing/afn107

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/025/CN-00640025/frame.html>

Record #324 of 370



ID: CN-00871640

AU: Feldman H

AU: Jones RW

AU: Kivipelto M

AU: Sparks L

AU: Doody R

AU: Waters D

TI: The LEADe Study: a randomized, controlled trial investigating the effect of atorvastatin on cognitive and global function in patients with mild-to-moderate Alzheimer's disease receiving background therapy of donepezil

SO: Neurology

YR: 2008

VL: 71

PG: 153-6

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/640/CN-00871640/frame.html>

Record #325 of 370



ID: CN-00688379

AU: Waldemar G

AU: Hyvärinen M

AU: Josiassen MK

AU: Kørner A

AU: Lehto H

AU: Wetterberg P

TI: Tolerability of switching from donepezil to memantine treatment in patients with moderate to severe Alzheimer's disease.

SO: International journal of geriatric psychiatry

YR: 2008

VL: 23

NO: 9

PG: 979-81

PM: PUBMED 18229874

PT: Letter; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [diagnosis] [drug therapy];Cholinesterase Inhibitors [adverse effects] [therapeutic use];Dopamine Agents [adverse effects] [therapeutic use];Double-Blind Method;Indans [adverse effects] [therapeutic use];Memantine [adverse effects] [therapeutic use];Piperidines [adverse effects] [therapeutic use];Severity of Illness Index;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1002/gps.1979

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/379/CN-00688379/frame.html>

Record #326 of 370



ID: CN-00730455

AU: Six L

AU: Leodolter S

AU: Sings HL

AU: Barr E

AU: Haupt R

AU: Joura EA

TI: Prevalence of human papillomavirus types 6, 11, 16 and 18 in young Austrian women - baseline data of a phase III vaccine trial.

SO: Wiener klinische Wochenschrift

YR: 2008

VL: 120

NO: 21-22

PG: 666-71

PM: PUBMED 19116707

PT: Clinical Trial, Phase III; Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Adolescent;Alphapapillomavirus [isolation & purification];Austria [epidemiology];Comorbidity;Double-Blind Method;Human papillomavirus 11 [isolation & purification];Human papillomavirus 16 [isolation & purification];Human papillomavirus 18 [isolation & purification];Human papillomavirus 6 [isolation & purification];Papillomavirus Infections [epidemiology] [microbiology] [prevention & control];Papillomavirus Vaccines [administration & dosage];Prevalence;Risk Assessment [methods];Risk Factors;Smoking [epidemiology];Vaccination [utilization];Women's Health;Adult[checkword];Female[checkword];Humans[checkword];Young Adult[checkword]

CC: SR-GYNAECA

DOI: 10.1007/s00508-008-1093-3

AB: INTRODUCTION: Cervical cancer is the second most common cancer among women worldwide. In the absence of changing risk or intervention, it is projected that in comparison with 2002 there will be a 40% increase in the number of new cases of cervical cancer by 2020. HPV types 16 and 18 cause 70% of cervical cancers worldwide, 50% of high-grade cervical intraepithelial neoplasias and 25% of low-grade neoplasias. HPV types 6 and 11 are the causative agent of > 90% of genital warts. The aim of this study was to assess the baseline prevalence of infection with HPV 6, 11, 16 and 18 in young Austrian women. METHODS: Austrian females aged 16-24 (n = 123) were enrolled in a double-blind, placebo-controlled, randomized phase III trial of a quadrivalent HPV (types 6, 11, 16, 18) vaccine (FUTURE I, ClinicalTrials.gov number NCT00092521). Healthy women who were not pregnant and had no prior history of genital warts or abnormal results on cervical cytologic testing and had fewer than five lifetime sex partners were eligible for enrollment. The study sub-population was recruited primarily from university settings. RESULTS: Analysis of the sexual history of the Austrian subjects showed that 92.7% (114/123) were non-virgins and 46.3% were current smokers. At enrollment, 15 (13.5%) had positive serological or PCR tests for HPV 6, 11, 16 or 18. Serologically, 14 (12.3%) of women were positive to HPV 6, 11, 16 or 18: of these, 13 (11.4%) were positive for HPV 16, four (3.5%) were positive for HPV 18, and one (0.9%) for HPV 6. By PCR all were negative for HPV 6 and 11, whereas seven (6.1%) were positive for HPV 16 and one (0.9%) for HPV 18. Abnormal cytology was observed in 12 (10.3%) women. DISCUSSION: Although the prevalence of vaccine HPV types among young Austrian women with fewer than five lifetime sexual partners was lower than in international data, we observed a high prevalence of abnormal cytology and smoking. These data suggest that a substantial number of Austrian women are at risk for HPV-related disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/455/CN-00730455/frame.html>

Record #327 of 370



ID: CN-00666530

AU: Straaten EC

AU: Harvey D

AU: Scheltens P

AU: Barkhof F

AU: Petersen RC

AU: Thal LJ

AU: Jack CR

AU: DeCarli C

TI: Periventricular white matter hyperintensities increase the likelihood of progression from amnesic mild cognitive impairment to dementia.

SO: Journal of neurology

YR: 2008

VL: 255

NO: 9

PG: 1302-8

PM: PUBMED 18825439

PT: Controlled Clinical Trial; Journal Article; Multicenter Study; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [pathology];Amnesia [drug therapy] [pathology];Antioxidants [therapeutic use];Atrophy;Brain [drug effects] [pathology];Cerebral Ventricles [drug effects] [pathology];Cholinesterase Inhibitors [therapeutic use];Cognition Disorders [drug therapy] [pathology];Dementia [drug therapy] [pathology];Disease Progression;Double-Blind Method;Image Processing, Computer-Assisted [methods];Indans [therapeutic use];Magnetic Resonance Imaging [methods];Piperidines [therapeutic use];Prospective Studies;Temporal Lobe [drug effects] [pathology];Time Factors;Treatment Outcome;Vitamin E [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1007/s00415-008-0874-y

AB: BACKGROUND: White matter hyperintensities (WMH) have an effect on cognition and are increased in severity among individuals with amnesic mild cognitive impairment (aMCI). The

influence of WMH on progression of aMCI to Alzheimer's disease (AD) is less clear. METHODS: Data were drawn from a three-year prospective, double blind, placebo controlled clinical trial that examined the effect of donepezil or vitamin E on progression from aMCI to AD. WMH from multiple brain regions were scored on MR images obtained at entry into the trial from a subset of 152 study participants using a standardized visual rating scale. Cox proportional hazards models adjusting for age, education and treatment arm were used to investigate the role of WMH on time to progression. RESULTS: 55 of the 152 (36.2 %) aMCI subjects progressed to AD. Only periventricular hyperintensities (PVH) were related to an increased risk of AD within three years (HR = 1.59, 95 % CI = 1.24 - 2.05, p-value < 0.001). Correcting for medial temporal lobe atrophy or the presence of lacunes did not change statistical significance. CONCLUSION: PVH are associated with an increased risk of progression from aMCI to AD. This suggests that PVH, an MRI finding thought to represent cerebrovascular damage, contributes to AD onset in vulnerable individuals independent of Alzheimer pathology.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/530/CN-00666530/frame.html>

Record #328 of 370



ID: CN-00650163

AU: Lannfelt L

AU: Blennow K

AU: Zetterberg H

AU: Batsman S

AU: Ames D

AU: Harrison J

AU: Masters CL

AU: Targum S

AU: Bush AI

AU: Murdoch R

AU: Wilson J

AU: Ritchie CW

TI: Safety, efficacy, and biomarker findings of PBT2 in targeting Abeta as a modifying therapy for Alzheimer's disease: a phase IIa, double-blind, randomised, placebo-controlled trial.

SO: Lancet neurology

YR: 2008

VL: 7

NO: 9

PG: 779-86

PM: PUBMED 18672400

PT: Clinical Trial, Phase II; Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy] [metabolism] [physiopathology]; Amyloid beta-Peptides [antagonists & inhibitors] [metabolism]; Biological Markers [analysis] [blood] [cerebrospinal fluid]; Brain [drug effects] [metabolism] [physiopathology]; Clioquinol [administration & dosage] [adverse effects] [analogs & derivatives] [chemistry] [pharmacology] [therapeutic use]; Dose-Response Relationship, Drug; Double-Blind Method; Down-Regulation [drug effects] [physiology]; Ionophores [administration & dosage] [adverse effects]; Metals [metabolism]; Peptide Fragments [antagonists & inhibitors] [metabolism]; Placebo Effect; Quinolines [administration & dosage] [adverse effects] [chemistry]; Safety; Treatment Outcome; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

CC: SR-DEMENTIA

DOI: 10.1016/S1474-4422(08)70167-4

AB: BACKGROUND: PBT2 is a metal-protein attenuating compound (MPAC) that affects the Cu²⁺(+)-mediated and Zn²⁺(+)-mediated toxic oligomerisation of Aβ seen in Alzheimer's disease (AD). Strong preclinical efficacy data and the completion of early, clinical safety studies have preceded this phase IIa study, the aim of which was to assess the effects of PBT2 on safety, efficacy, and biomarkers of AD. METHODS: Between December 6, 2006, and September 21, 2007, community-dwelling patients over age 55 years were recruited to this 12-week, double-blind, randomised trial of PBT2. Patients were randomly allocated to receive 50 mg PBT2, 250 mg PBT2, or placebo. Inclusion criteria were early AD (mini-mental state examination [MMSE] score between 20 and 26 points or Alzheimer's disease assessment scale-cognitive subscale (ADAS-cog) score between 10 and 25 points), taking a stable dose of acetylcholinesterase inhibitor (donepezil, galantamine, or rivastigmine) for at least 4 months, a modified Hachinski score of 4 points or less, and CT or MRI results that were consistent with AD. The principal outcomes were safety and tolerability. Secondary outcomes were plasma and CSF biomarkers and cognition. Analysis was intention to treat. The trial is registered with ClinicalTrials.gov, number NCT00471211. FINDINGS: 78 patients were randomly assigned (29 to placebo, 20 to PBT2 50 mg, and 29 to PBT2 250 mg) and 74 (95%) completed the study. 42 (54%) patients had at least one treatment emergent adverse event (10 [50%] on PBT2 50 mg,

18 [62%] on PBT2 250 mg, and 14 [48%] on placebo). No serious adverse events were reported by patients on PBT2. Patients treated with PBT2 250 mg had a dose-dependent ($p=0.023$) and significant reduction in CSF Abeta(42) concentration compared with those treated with placebo (difference in least squares mean change from baseline was -56.0 pg/mL, 95% CI -101.5 to -11.0 ; $p=0.006$). PBT2 had no effect on plasma biomarkers of AD or serum Zn(2+) and Cu(2+) concentrations. Cognition testing included ADAS-cog, MMSE, and a neuropsychological test battery (NTB). Of these tests, two executive function component tests of the NTB showed significant improvement over placebo in the PBT2 250 mg group: category fluency test (2.8 words, 0.1 to 5.4; $p=0.041$) and trail making part B (-48.0 s, -83.0 to -13.0 ; $p=0.009$). INTERPRETATION: The safety profile is favourable for the ongoing development of PBT2. The effect on putative biomarkers for AD in CSF but not in plasma is suggestive of a central effect of the drug on Abeta metabolism. Cognitive efficacy was restricted to two measures of executive function. Future trials that are larger and longer will establish if the effects of PBT2 on biomarkers and cognition that are reported here translate into clinical effectiveness.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/163/CN-00650163/frame.html>

Record #329 of 370



ID: CN-00622257

AU: Fleisher AS

AU: Sun S

AU: Taylor C

AU: Ward CP

AU: Gamst AC

AU: Petersen RC

AU: Jack CR

AU: Aisen PS

AU: Thal LJ

TI: Volumetric MRI vs clinical predictors of Alzheimer disease in mild cognitive impairment.

SO: Neurology

YR: 2008

VL: 70

NO: 3

PG: 191-9

PM: PUBMED 18195264

PT: Comparative Study; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [diagnosis] [genetics] [psychology]; Apolipoproteins E [genetics]; Brain [pathology] [physiopathology]; Cerebral Ventricles [pathology]; Cognition Disorders [complications] [diagnosis] [genetics]; Cohort Studies; DNA Mutational Analysis; Demography; Disease Progression; Entorhinal Cortex [pathology] [physiopathology]; Genetic Testing; Genotype; Hippocampus [pathology] [physiopathology]; Magnetic Resonance Imaging [methods] [standards]; Neuropsychological Tests [standards]; Predictive Value of Tests; Sensitivity and Specificity; Aged[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

DOI: 10.1212/01.wnl.0000287091.57376.65

AB: OBJECTIVE: To compare volumetric MRI of whole brain and medial temporal lobe structures to clinical measures for predicting progression from amnesic mild cognitive impairment (MCI) to Alzheimer disease (AD). METHODS: Baseline MRI scans from 129 subjects with amnesic MCI were obtained from participants in the Alzheimer's Disease Cooperative Study group's randomized, placebo-controlled clinical drug trial of donepezil, vitamin E, or placebo. Measures of whole brain, ventricular, hippocampal, and entorhinal cortex volumes were acquired. Participants were followed with clinical and cognitive evaluations until formal criteria for AD were met, or completion of 36 months of follow-up. Logistic regression modeling was done to assess the predictive value of all MRI measures, risk factors such as APOE genotype, age, family history of AD, education, sex, and cognitive test scores for progression to AD. Least angle regression modeling was used to determine which variables would produce an optimal predictive model, and whether adding MRI measures to a model with only clinical measures would improve predictive accuracy. RESULTS: Of the four MRI measures evaluated, only ventricular volumes and hippocampal volumes were predictive of progression to AD. Maximal predictive accuracy using only MRI measures was obtained by hippocampal volumes by themselves (60.4%). When clinical variables were added to the model, the predictive accuracy increased to 78.8%. Use of MRI measures did not improve predictive accuracy beyond that obtained by cognitive measures alone. APOE status, MRI, or demographic variables were not necessary for the optimal predictive model. This optimal model included the Delayed 10-word list recall, New York University Delayed Paragraph Recall, and the Alzheimer's Disease Assessment Scale-Cognitive Subscale total score. CONCLUSION: In moderate stages of amnesic mild cognitive impairment, common cognitive tests provide better predictive accuracy than measures of whole brain, ventricular, entorhinal cortex, or hippocampal volumes for assessing progression to Alzheimer disease.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/257/CN-00622257/frame.html>

Record #330 of 370



ID: CN-00630233

AU: Porsteinsson AP

AU: Grossberg GT

AU: Mintzer J

AU: Olin JT

TI: Memantine treatment in patients with mild to moderate Alzheimer's disease already receiving a cholinesterase inhibitor: a randomized, double-blind, placebo-controlled trial.

SO: Current Alzheimer research

YR: 2008

VL: 5

NO: 1

PG: 83-9

PM: PUBMED 18288936

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [drug therapy] [psychology];Cholinesterase Inhibitors [therapeutic use];Double-Blind Method;Drug Therapy, Combination;Excitatory Amino Acid Antagonists [therapeutic use];Memantine [therapeutic use];Mental Status Schedule;Neuropsychological Tests;Prospective Studies;Receptors, N-Methyl-D-Aspartate [antagonists & inhibitors];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Humans[checkword];Middle Aged[checkword]

CC: SR-DEMENTIA: SR-HTN

AB: OBJECTIVE: To evaluate the efficacy and safety of memantine in patients with mild to moderate Alzheimer's disease (AD) receiving cholinesterase inhibitor (ChEI) treatment. METHODS: Participants (N= 433) with probable AD, Mini-Mental State Exam (MMSE) scores between 10-22 (inclusive), and concurrent stable use of ChEIs (donepezil, rivastigmine, galantamine) were randomized to placebo or memantine (20 mg once daily) for 24 weeks. Primary outcomes were changes from baseline on the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and on Clinician's Interview-Based Impression of Change Plus Caregiver Input (CIBIC-Plus) score. Secondary measures comprised the 23-item Alzheimer

Disease Cooperative Study-Activities of Daily Living Scale (ADCS-ADL(23)), Neuropsychiatric Inventory (NPI), and MMSE. RESULTS: At the end of the trial, there were no statistically significant differences between the memantine- and placebo group on primary and secondary outcome measures. The incidence of adverse events (AEs) was similar between the two groups, with no AE occurring in more than 5% of memantine-treated patients and at a rate twice that of the placebo group. CONCLUSIONS: In this trial, memantine did not show an advantage over placebo based on protocol-specified primary or secondary analyses in patients with mild to moderate AD on stable ChEI regimens. There were no significant differences in tolerability and safety between the memantine- and placebo groups.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/233/CN-00630233/frame.html>

Record #331 of 370



ID: CN-00707922

AU: El-Khatib MF

AU: Zeineldine SM

AU: Jamaledine GW

TI: Effect of pressure support ventilation and positive end expiratory pressure on the rapid shallow breathing index in intensive care unit patients.

SO: Intensive care medicine

YR: 2008

VL: 34

NO: 3

PG: 505-10

XR: EMBASE 2008213462

PT: Journal: Article

KY: adult // aged // ambient air // article // *artificial ventilation // breathing rate // clinical article // clinical trial // comparative study // controlled study // female // human // *intensive care unit // male // *positive end expiratory pressure // *pressure support ventilation // prospective study // statistical significance // tidal volume // university hospital // ventilated patient // ventilator

DOI: 10.1007/s00134-007-0939-x

AB: Objective: We compared rapid shallow breathing index (RSBI) values under various ventilatory support settings prior to extubation. Design and setting: Prospective study in the intensive care unit at a university hospital. Patients: Thirty six patients ready for extubation. Interventions: Patients were enrolled when receiving pressure support ventilation (PSV) of 5 cmH₂O, PEEP of 5 cmH₂O, and FIO₂ of 40% (PS). Subsequently each patient received a trial of PSV of 0 cmH₂O, PEEP of 5 cmH₂O, and FIO₂ of 40% (CPAP), a trial of PSV of 0 cmH₂O, PEEP of 5 cmH₂O and FIO₂ of 21% (CPAP-R/A), and a 1-minute spontaneously breathing room air trial off the ventilator (T-piece). Trials were carried out in random order. Measurements and results: Respiratory frequency (f) and tidal volume (V_T) were measured during PS, CPAP, CPAP-R/A, and T-piece in all patients. RSBI (f/V_T) was determined for each patient under all experimental conditions, and the average RSBI was compared during PS, CPAP, CPAP-R/A, and T-piece. RSBI was significantly smaller during PS (46 + 8bpm/l), CPAP (63 + 13bpm/l) and CPAP-R/A (67 + 14bpm/l) vs. T-piece (100 + 23bpm/l). There was no significant difference in RSBI between CPAP and CPAP-R/A. RSBI during CPAP and CPAP-R/A were significantly smaller than RSBI during T-piece. In all patients RSBI values were less than 105 bpm/l during PS, CPAP, and CPAP-R/A. However, during T-piece the RSBI increased to greater than 105 bpm/l in 13 of 36 patients. Conclusions: In the same patient the use of PSV and/or PEEP as low as 5 cmH₂O can influence the RSBI. In contrast, changes in FIO₂ may have no effect on the RSBI. 2007 Springer-Verlag.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/922/CN-00707922/frame.html>

Record #332 of 370



ID: CN-00617483

AU: Sampson EL

AU: Raven PR

AU: Ndhlovu PN

AU: Vallance A

AU: Garlick N

AU: Watts J

AU: Blanchard MR

AU: Bruce A

AU: Blizard R

AU: Ritchie CW

TI: A randomized, double-blind, placebo-controlled trial of donepezil hydrochloride (Aricept) for reducing the incidence of postoperative delirium after elective total hip replacement.

SO: International journal of geriatric psychiatry

YR: 2007

VL: 22

NO: 4

PG: 343-9

PM: PUBMED 17006875

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Arthroplasty, Replacement, Hip; Delirium [diagnosis] [drug therapy]; Double-Blind Method; England; Hospitals, Teaching; Incidence; Indans [adverse effects] [therapeutic use]; Length of Stay; Mental Status Schedule; Nootropic Agents [adverse effects] [therapeutic use]; Odds Ratio; Piperidines [adverse effects] [therapeutic use]; Postoperative Complications [diagnosis] [drug therapy]; Surgical Procedures, Elective; Treatment Outcome; Aged[checkword]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

DOI: 10.1002/gps.1679

AB: OBJECTIVES: This was a pilot, phase 2a study to assess methodological feasibility and the safety and efficacy of donepezil in preventing postoperative delirium after elective total hip replacement surgery in older people without pre-existing dementia. The hypothesis was that donepezil would reduce the incidence of postoperative delirium. METHODS: A double blind, placebo controlled, parallel group randomized trial was undertaken. Patients were block randomized pre-operatively to receive placebo or donepezil 5 mg immediately following surgery and every 24 h thereafter for a further three days. The main outcome was the incidence of delirium (using the Delirium Symptom Interview). The secondary outcome was length of hospital stay. RESULTS: Thirty-three patients (mean age 67 years; 17 males, 16 females) completed the study (19 donepezil, 14 placebo). Donepezil was well tolerated with no serious adverse events. Postoperative delirium occurred in 21.2% of subjects. Donepezil did not significantly reduce the incidence of delirium. The unadjusted risk ratio (donepezil vs placebo) for delirium was 0.29 (95% CI = 0.06,1.30) (χ^2 ([1]) = 3.06; p = 0.08). Mean length of hospital stay was 9.9 days for the donepezil group vs 12.1 days in the placebo group; difference in means = -2.2 days (95% CI = -0.39,4.78) (t ([31]) = 1.73; p = 0.09). CONCLUSIONS: The experimental paradigm was feasible and acceptable. Donepezil did not significantly reduce the incidence of delirium or length of hospital stay, however for both outcomes there was a consistent trend suggesting possible benefit. The sample size required for a definitive trial (99% power, α 0.05) would be 95 subjects per arm.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/483/CN-00617483/frame.html>

Record #333 of 370



ID: CN-00714151

AU: NCT00457769

TI: [Public title] Aricept to improve functional tasks in vascular dementia; [Official title] Phase 1 study of Aricept plus a behavioral strategy to improve functional tasks in vascular dementia

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/151/CN-00714151/frame.html>

Record #334 of 370



ID: CN-00724678

AU: Anon

TI: Aricept to improve functional tasks in vascular dementia or phase 1 study of aricept plus a behavioral strategy to improve functional tasks in vascular dementia

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/678/CN-00724678/frame.html>

Record #335 of 370



ID: CN-00590472

AU: Black SE

AU: Doody R

AU: Li H

AU: McRae T

AU: Jambor KM

AU: Xu Y

AU: Sun Y

AU: Perdomo CA

AU: Richardson S

TI: Donepezil preserves cognition and global function in patients with severe Alzheimer disease.

SO: Neurology

YR: 2007

VL: 69

NO: 5

PG: 459-69

PM: PUBMED 17664405

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living;Alzheimer Disease [drug therapy] [physiopathology] [psychology];Caregivers [statistics & numerical data];Cholinesterase Inhibitors [administration & dosage] [adverse effects];Cognition [drug effects] [physiology];Cognition Disorders [drug therapy] [etiology] [physiopathology];Disease Progression;Double-Blind Method;Indans [administration & dosage] [adverse effects];Neuropsychological Tests;Piperidines [administration & dosage] [adverse effects];Placebos;Questionnaires;Recovery of Function [drug effects] [physiology];Severity of Illness Index;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1212/01.wnl.0000266627.96040.5a

AB: OBJECTIVE: To evaluate the efficacy and safety of donepezil for severe Alzheimer disease (AD). METHODS: Patients with severe AD (Mini-Mental State Examination [MMSE] scores 1 to 12 and Functional Assessment Staging [FAST] scores ≥ 6) were enrolled in this multinational, double-blind, placebo-controlled trial at 98 sites. Patients were randomized to donepezil 10 mg daily or placebo for 24 weeks. Primary endpoints were the Severe Impairment Battery (SIB) and Clinician's Interview-Based Impression of Change-Plus caregiver input (CIBIC-Plus). Secondary endpoints included the MMSE, the Alzheimer Disease Cooperative Study-Activities of Daily Living-severe version (ADCS-ADL-sev), the Neuropsychiatric Inventory (NPI), the Caregiver Burden Questionnaire (CBQ), and the Resource Utilization for Severe Alzheimer Disease Patients (RUSP). Efficacy analyses were performed in the intent-to-treat (ITT) population using last post-baseline observation carried forward (LOCF). Safety assessments were performed for patients receiving ≥ 1 dose of donepezil or placebo. RESULTS: Patients were randomized to donepezil ($n = 176$) or placebo ($n = 167$). Donepezil was superior to placebo on SIB score change from baseline to endpoint (least squares mean difference 5.32; $p = 0.0001$). CIBIC-Plus and MMSE scores favored donepezil at endpoint ($p = 0.0473$ and $p = 0.0267$). Donepezil was not significantly different from placebo on the ADCS-ADL-sev, NPI, CBQ, or RUSP. Adverse events reported were consistent with the known cholinergic effects of donepezil and with the safety profile in patients with mild to moderate AD. CONCLUSION: Patients with severe AD demonstrated greater efficacy compared to placebo on measures of cognition and global function.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/472/CN-00590472/frame.html>

Record #336 of 370



ID: CN-00609828

AU: Doraiswamy PM

AU: Babyak MA

AU: Hennig T

AU: Trivedi R

AU: White WD

AU: Mathew JP

AU: Newman MF

AU: Blumenthal JA

TI: Donepezil for cognitive decline following coronary artery bypass surgery: a pilot randomized controlled trial.

SO: Psychopharmacology bulletin

YR: 2007

VL: 40

NO: 2

PG: 54-62

PM: PUBMED 17514186

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Cardiopulmonary Bypass [adverse effects] [psychology]; Cognition Disorders [diagnosis] [drug therapy]; Coronary Artery Bypass [adverse effects] [psychology]; Dose-Response Relationship, Drug; Double-Blind Method; Drug Administration Schedule; Electrocardiography [drug effects]; Follow-Up Studies; Indans [adverse effects] [therapeutic use]; Memory, Short-Term [drug effects]; Mental Recall [drug effects]; Neuropsychological Tests; Nootropic Agents [adverse effects] [therapeutic use]; Piperidines [adverse effects] [therapeutic use]; Postoperative Complications [diagnosis] [drug therapy]; Wechsler Scales; Aged[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

CC: SR-VASC

AB: OBJECTIVE: To study the effect of donepezil in treating patients with cognitive decline following coronary artery bypass graft (CABG) surgery. METHODS: Forty-four patients, with at least a 0.5 SD decline at 1 year post-CABG on at least one cognitive domain compared to their pre-CABG baseline score, were randomized to treatment with donepezil (titrated to 10 mg daily) or placebo in a 12-week double-blind, single center, randomized study. A composite cognitive change score served as the primary outcome. Secondary outcome measures included tests of memory, attention, psychomotor speed, and executive function. RESULTS: The composite cognitive outcome did not show significant treatment effects. Secondary measures varied in their sensitivity to donepezil effects with the largest effects seen on the Wechsler Visual Memory Scale-Delayed and Immediate recall tests. More than twice (52% vs. 22%) as many donepezil-treated patients showed a significant improvement compared with placebo patients on Delayed recall. Tests with weak effect sizes and minimal trends favoring donepezil were the Boston Naming and Digit Symbol. However, most of the other instruments (e.g., Digit Span, Trails B, and Controlled Word Association) showed no treatment benefits. More donepezil-treated than placebo-treated patients experienced diarrhea, but other adverse effects and safety measures did not differ between groups. CONCLUSION: In the post-CABG mild cognitive decline setting, donepezil did not improve composite cognitive performance but improved some aspects of memory. Donepezil was well tolerated and had no significant effects on EKG parameters. Because of limitations such as small sample size and multiplicity of tests, these findings are preliminary but add to our knowledge of cholinergic effects in vascular mild cognitive decline.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/828/CN-00609828/frame.html>

Record #337 of 370



ID: CN-00640778

AU: Matsuda O

TI: Cognitive stimulation therapy for Alzheimer's disease: The effect of cognitive stimulation therapy on the progression of mild Alzheimer's disease in patients treated with donepezil.

SO: International Psychogeriatrics

YR: 2007

VL: 19

NO: 2

PG: 241-52

XR: EMBASE 2007128090

PT: Journal: Article

KY: adult // *Alzheimer disease/dt [Drug Therapy] // *Alzheimer disease/th [Therapy] // article // *brain depth stimulation // clinical article // clinical trial // *cognition // *cognitive defect // cognitive rehabilitation // controlled clinical trial // controlled study // data analysis // disease course // follow up // human // Mini Mental State Examination // randomized controlled trial // scoring system // statistical significance // treatment duration // treatment outcome // cholinesterase inhibitor // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy] // *donepezil/po [Oral Drug Administration]

DOI: 10.1017/S1041610206004194

AB: Background: There is general consensus regarding the benefit of acetylcholinesterase inhibitors (e.g. donepezil) in Alzheimer's disease (AD). However, the combined effect of acetylcholinesterase and cognitive stimulation therapy (CST) is still controversial. Objective: This study examines their combined effect on the progression of cognitive decline in AD by comparing the cognitive performance of 17 AD patients treated with CST and donepezil (combined treatment group) and 13 AD patients treated with donepezil alone (control group). Methods: Patients in the combined treatment group received 5 mg of donepezil per day and about 20 one-hour CST sessions for one year, whereas the control group received only 5 mg of donepezil per day. The first eight sessions were carried out once a week, and subsequent sessions were generally once every two weeks. The patients were evaluated for changes in cognitive ability by administering the Mini-mental State Examination (MMSE) before the start

of CST (baseline) and about one year later (follow-up). Results: A repeated-measure analysis of variance revealed a significant group x time interaction. The MMSE score decreased significantly in the control group, but did not change significantly in the combined treatment group. Three patients in the control group declined by four points on the MMSE, compared to none in the combined treatment group. Effect size (ES) in the control group was relatively large and negative, while the ES in the combined treatment group was close to zero. Conclusions: The results suggest the possibility that donepezil plus CST slowed the rate of cognitive decline more than the administration of donepezil alone. 2006 International Psychogeriatric Association.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/778/CN-00640778/frame.html>

Record #338 of 370



ID: CN-00665089

AU: Yan YX

AU: Liang LZ

AU: Zhou ZL

TI: [Clinical study of combined treatment with compound Reinhartdt and Sea Cumber Capsule and donepezil for vascular dementia].

SO: Zhongguo Zhong xi yi jie he za zhi [Chinese journal of integrated traditional and Western medicine]

YR: 2007

VL: 27

NO: 10

PG: 887-90

PM: PUBMED 17990453

PT: English Abstract; Journal Article; Randomized Controlled Trial

KY: Capsules;Dementia, Vascular [drug therapy];Drug Therapy, Combination;Drugs, Chinese Herbal [therapeutic use];Indans [therapeutic use];Materia Medica [therapeutic use];Medicine, Chinese Traditional;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-COMP MED

AB: OBJECTIVE: To study the efficacy and safety of the combined treatment with compound Reinhartdt and Sea Cumber Capsule (RSC, a Chinese medicinal preparation consisted mainly of Reinhartdt and Sea Cumber) and Donepezil for vascular dementia (VD), and its effect on thyroid function axis. METHODS: Sixty-three patients with VD were treated respectively with RSC, Donepezil and the combined treatment. MMSE, ADAS-Cog and ADL scales were used to evaluate the condition of patients before treatment as well as at 3 months and 6 months after treatment. Meanwhile, levels of thyroid hormones, including (TSH, FT3, FT4, TT3, TT4) were measured with radioimmunoassay. RESULTS: As compared with the baseline, MMSE score increased, ADAS-Cog score and ADL score decreased significantly in all the three groups after 3 months and 6 months of treatment ($P < 0.05$, $P < 0.01$), the improvement in the Donepezil group was more significant than that in the RSC group after 6 months of treatment ($P < 0.05$), but the combined treatment group showed the best efficacy ($P < 0.01$). After 3 months of treatment, the levels of FT3 and FT4 in the combined treatment group increased, but showed no statistical significance ($P > 0.05$). However, significant changes were found at 6 months after combined treatment ($P < 0.01$). No significant changes were seen at all in levels of TSH, TT3 and TT4 ($P > 0.05$). FT3, FT4 increased without statistical significance after 6 months Donepezil treatment, TSH, TT3 and TT4 also showed no significant difference in the Donepezil group and no other significant changes of thyroid hormones was seen in patients treated with RSC ($P > 0.05$). No obvious adverse reaction occurred in any of the three groups. CONCLUSION: Combined treatment of RSC and Donepezil was effective and safe on VD patient, with the efficacy much better than either of them alone. No significant adverse reaction was observed. The regulation on thyroid hormones may one of the mechanisms of the combined treatment in improving cognitive function.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/089/CN-00665089/frame.html>

Record #339 of 370



ID: CN-00627091

AU: Zhou ZL

AU: Liang LZ

AU: Yan YX

TI: [Clinical study of Reinhartdt and sea cucumber capsule combined with donepezil in treating Alzheimer's disease].

SO: Zhongguo Zhong xi yi jie he za zhi [Chinese journal of integrated traditional and Western medicine]

YR: 2007

VL: 27

NO: 2

PG: 110-3

PM: PUBMED 17342994

PT: English Abstract; Journal Article; Randomized Controlled Trial

KY: Alzheimer Disease [drug therapy];Capsules;Drug Therapy, Combination;Indans [therapeutic use];Medicine, Chinese Traditional;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Radioimmunoassay;Sea Cucumbers [chemistry];Thyroid Hormones [blood];Aged[checkword];Aged, 80 and over[checkword];Animals[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-COMP MED

AB: OBJECTIVE: To study the efficacy and safety of Reinhartdt and sea cucumber capsule (RSC) combined with donepezil in treating Alzheimer's disease (AD), and its effect on thyroid function axis. METHODS: Sixty-eight patients were randomly assigned to the RSC group, the Donepezil group and the combined treatment group, who were treated for 3 and 6 months with RSC, Donepezil and RSC combined with Donepezil, respectively. The curative effect was evaluated by scoring according to Mini-Mental State Examination (MMSE), ADAS-Cog and ADL chart, and the level of thyroid hormones, including TSH, FT3, FT4, TT3 and TT4, were measured with radioimmunoassay before treatment, 3 and 6 months after treatment respectively.

RESULTS: As compared with the baseline, MMSE score increased, ADAS-Cog score and ADL score decreased significantly in all the three groups after 3 months and 6 months of treatment ($P < 0.05$ and $P < 0.01$), but the improvement in the combined treatment group was more significant than that in the other two groups ($P < 0.01$). After 6 months of treatment, the levels of FT3 and FT4 in the combined treatment group were significantly changed ($P < 0.01$), but no significant change in all the thyroid hormones was found in the other two groups. No obvious adverse reaction occurred in all the three groups. CONCLUSION: RSC combined with Donepezil in treating AD is effective and safe with no evident adverse reaction, better than single drug treatment, which may be through influencing the metabolism of thyroid hormones to improve the cognition function of AD patients.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/091/CN-00627091/frame.html>

Record #340 of 370



ID: CN-00641415

AU: Ozenli Y

AU: Yagci D

AU: Karaca S

TI: Efficacy of donepezil on cognitive functions in mild cognitive impairment.

SO: Klinik Psikofarmakoloji Bulteni

YR: 2007

VL: 17

NO: 2

PG: 62-7

XR: EMBASE 2007321120

PT: Journal: Article

KY: adult // aged // article // clinical article // clinical trial // *cognition // *cognitive defect/dt [Drug Therapy] // controlled clinical trial // controlled study // drug efficacy // female // human // male // memory // nausea/si [Side Effect] // randomized controlled trial // sedation // side effect/si [Side Effect] // verbal memory // vomiting/si [Side Effect] // Wechsler Memory Scale // *donepezil/ae [Adverse Drug Reaction] // *donepezil/ct [Clinical Trial] // *donepezil/dt [Drug Therapy]

CC: SR-BEHAV

AB: Objective: The condition characterized by clinically distinctive cognitive impairment and likely to affect occupational and social functioning is known as Mild Cognitive Impairment (MCI). Acetylcholinesterase inhibitors have been used for the treatment of MCI up to now. However, there have been few studies to show the efficacy of these drugs on cognitive functions. The aim of this study was to investigate the effects of donepezil on cognitive functions in patients with MCI. Method: This study included 51 patients. 26 patients were randomized to the study group and 25 to the control group. The study group received donepezil HCl for 24 weeks. The control group did not receive any psychotropic drugs. Cognitive functions of all patients were evaluated by seven subscales of the Wechsler Memory Scale-Revised (WMS-R) at baseline, 4th week and 24th week of the study. Results: There was a significant difference in figural memory, verbal paired associates and logical memory subscale scores between the groups ($p < 0,001$). Although there was an improvement in verbal paired associates and logical memory subscale scores in the study group, there was a decrease on the figural memory test scores. Conclusion: It was found that donepezil led to an improvement especially in memory and attention in MCI. The decrease in figural memory scores can be explained by the fact that donepezil does not exert the same effect on all areas of the brain.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/415/CN-00641415/frame.html>

Record #341 of 370



ID: CN-00586157

AU: Lee BJ

AU: Lee JG

AU: Kim YH

TI: A 12-week, double-blind, placebo-controlled trial of donepezil as an adjunct to haloperidol for treating cognitive impairments in patients with chronic schizophrenia.

SO: Journal of psychopharmacology (Oxford, England)

YR: 2007

VL: 21

NO: 4

PG: 421-7

PM: PUBMED 17092979

PT: Journal Article; Randomized Controlled Trial

KY: Antipsychotic Agents [therapeutic use];Cholinesterase Inhibitors [therapeutic use];Chronic Disease;Cognition Disorders [drug therapy] [etiology];Double-Blind Method;Drug Therapy, Combination;Haloperidol [therapeutic use];Indans [therapeutic use];Piperidines [therapeutic use];Schizophrenia [complications] [drug therapy];Schizophrenic Psychology;Treatment Outcome;Adult[checkword];Humans[checkword]

CC: SR-DEMENTIA: SR-SCHIZ

DOI: 10.1177/0269881106070996

AB: To study the effects of acetylcholinesterase inhibitors (AChEIs) in the management of cognitive impairments in patients with schizophrenia, we investigated the effects of 12 weeks of adjunctive therapy with donepezil on their cognitive impairments. Twenty-four subjects stabilized on haloperidol treatment (5-30 mg/day) for a minimum of 3 months were entered into a double-blind, placebo-controlled trial of donepezil as an adjunctive treatment. Subjects were randomly assigned under double-blind conditions to receive either 5 mg/day donepezil (N = 12) or placebo (N = 12) for 12 weeks. The subjects were evaluated at baseline, and after 4, 8, and 12 weeks using the Korean version of Mini Mental State Examination (K-MMSE), Brief Psychiatric Rating Scale (BPRS), and standard neuropsychological assessment. The K-MMSE scores improved significantly ($p < 0.05$) but the BPRS scores did not improve significantly in

patients given donepezil; subjects showed slight improvement in several cognitive measures. At the end of the study, the difference in the mean K-MMSE scores between the donepezil and placebo groups approached statistical significance ($p = 0.056$). Of the several domains of cognitive functions assessed, verbal recognition and visual recall memory improved significantly ($p < 0.05$). But donepezil did not affect scores in the executive function tests. Our findings support a potential positive effect of AChEIs in the management of cognitive impairments in patients with chronic schizophrenia. Further studies with large subjects are needed to confirm our findings.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/157/CN-00586157/frame.html>

Record #342 of 370



ID: CN-00704025

AU: Winstein CJ

AU: Bentzen KR

AU: Boyd L

AU: Schneider LS

TI: Does the cholinesterase inhibitor, donepezil, benefit both declarative and non-declarative processes in mild to moderate Alzheimer's disease?

SO: Current Alzheimer research

YR: 2007

VL: 4

NO: 3

PG: 273-6


PM: PUBMED 17627484

PT: Clinical Trial; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [drug therapy]; Analysis of Variance; Cholinesterase Inhibitors [therapeutic use]; Double-Blind Method; Indans [therapeutic use]; Learning [drug effects]; Neuropsychological Tests; Pilot Projects; Piperidines [therapeutic use]; Psychomotor Performance [drug effects]; Reaction Time [drug effects]; Aged, 80 and over[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

AB: Previous research suggests separate neural networks for implicit (non-declarative) and explicit (declarative) memory processes. A core cognitive impairment in mild to moderate Alzheimer's disease (AD) is a pronounced declarative memory and learning deficit with relative preservation of non-declarative memory. Cholinesterase inhibitors has been purported to enhance cognitive function, and previous clinical trials consistently showed that donepezil, a reversible inhibitor of acetylcholinesterase (AChE), led to statistically significant improvements in cognition and patient function. This prospective pilot study is a randomized, double blind, placebo-controlled clinical trial investigating 10 patients with AD. Our purpose was to examine the relationship between declarative and non-declarative capability with particular emphasis on implicit sequence learning. Patients were assessed at baseline and again at 4-weeks. After participants' baseline data were obtained, each was double-blindly randomized to one of two groups: donepezil or placebo. At baseline participants were tested with two outcome measures (Serial Reaction Time Task, Alzheimer's Disease Assessment Scale-Cognitive Subscale). Participants were given either 5 mg donepezil or an identically appearing placebo to be taken nightly for 4 weeks (28 tablets), and then retested. The donepezil group demonstrated a greater likelihood of increases in both non-declarative and declarative processes. The placebo group was mixed without clearly definable trends or patterns. When the data were examined for coincidental changes in the two outcome measures together they are suggestive of a benefit from donepezil treatment for non-declarative and declarative processes.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/025/CN-00704025/frame.html>

Record #343 of 370 

ID: CN-00617598

AU: Burns A

AU: Gauthier S

AU: Perdomo C

TI: Efficacy and safety of donepezil over 3 years: an open-label, multicentre study in patients with Alzheimer's disease.

SO: International journal of geriatric psychiatry

YR: 2007

VL: 22

NO: 8

PG: 806-12

PM: PUBMED 17199235

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Alzheimer Disease [diagnosis] [drug therapy] [psychology];Dose-Response Relationship, Drug;Follow-Up Studies;Indans [adverse effects] [therapeutic use];Long-Term Care;Neuropsychological Tests;Nootropic Agents [adverse effects] [therapeutic use];Piperidines [adverse effects] [therapeutic use];Single-Blind Method;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1002/gps.1746

AB: OBJECTIVE: This 132-week, open-label extension study assessed the long-term efficacy and safety of donepezil in 579 patients with mild to moderate Alzheimer's disease (AD) who had previously participated in a 24-week double-blind study of 5 or 10 mg/day donepezil vs placebo. METHOD: Patients enrolled in the present study had a 6-week single-blind placebo washout period followed by treatment with donepezil 5 mg/day for 6 weeks with an optional increase in dosage to 10 mg/day between weeks 6 and 32. RESULTS: After 6 weeks of open-label treatment with donepezil 5 mg/day, mean Alzheimer's Disease Assessment Scale -- cognitive subscale scores (ADAS-cog) improved by approximately two points, while after 12 weeks of open-label treatment (with a majority of patients receiving 10 mg/day), the mean ADAS-cog score was 1 point better than the score at the end of the placebo washout period. Scores then declined gradually over the remainder of the study. Mean changes in Clinical Dementia Rating-Sum of Boxes scores showed slight improvement over the first 12 weeks of open-label treatment and then slowly declined for the remainder of the study period. Donepezil was well tolerated over the entire 162-week study period. Overall, 85% of patients experienced at least one adverse event (AE). The most common included diarrhoea (12%), nausea (11%), infection (11%) and accidental injury (10%). Some patients discontinued the study due to AEs (15%). CONCLUSIONS: These results support the conclusion that donepezil is safe and effective for the long-term treatment of patients with mild to moderate AD.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/598/CN-00617598/frame.html>

Record #344 of 370



ID: CN-00587578

AU: Risch SC

AU: Horner MD

AU: McGurk SR

AU: Palecko S

AU: Markowitz JS

AU: Nahas Z

AU: DeVane CL

TI: Double-blind donepezil-placebo crossover augmentation study of atypical antipsychotics in chronic, stable schizophrenia: a pilot study.

SO: Schizophrenia research

YR: 2007

VL: 93

NO: 1-3

PG: 131-5

PM: PUBMED 17391930

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Antipsychotic Agents [administration & dosage] [adverse effects];Benzodiazepines [administration & dosage] [adverse effects];Cholinesterase Inhibitors [administration & dosage] [adverse effects];Clozapine [administration & dosage] [adverse effects];Cross-Over Studies;Double-Blind Method;Drug Therapy, Combination;Indans [administration & dosage] [adverse effects];Nootropic Agents [administration & dosage] [adverse effects];Piperidines [administration & dosage] [adverse effects];Psychiatric Status Rating Scales;Psychotic Disorders [diagnosis] [drug therapy] [psychology];Risperidone [administration & dosage] [adverse effects];Schizophrenia [diagnosis] [drug therapy];Schizophrenic Psychology;Treatment Outcome;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-SCHIZ

DOI: 10.1016/j.schres.2007.01.001

AB: Thirteen outpatients with chronic but stable schizophrenia received donepezil and placebo augmentation of their maintenance antipsychotic medication regimen. Each subject received in a randomized, counterbalanced order 1) donepezil 5 mg for 6 weeks then donepezil 10 mg for six weeks and 2) placebo donepezil for 12 weeks. Serial ratings of the Positive and Negative Symptom Scale (PANSS) [Kay, S.R., Fiszbein, A., Opler, L.A., 1987. The positive and negative syndrome scale (PANSS) for schizophrenia. Schizophrenia Bulletin 13(2): 261-276] were performed by a trained rater blind to the donepezil order and condition: at baseline, 12 weeks and 24 weeks. On donepezil as compared to baseline or placebo, there was a significant

improvement in PANSS negative scores ($p=.018$, $n=13$). These results are discussed with respect to other studies using cholinesterase inhibitors as an augmentation strategy in schizophrenia.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/578/CN-00587578/frame.html>

Record #345 of 370



ID: CN-00588630

AU: Hamberger MJ

AU: Palmese CA

AU: Scarneas N

AU: Weintraub D

AU: Choi H

AU: Hirsch LJ

TI: A randomized, double-blind, placebo-controlled trial of donepezil to improve memory in epilepsy.

SO: Epilepsia

YR: 2007

VL: 48

NO: 7

PG: 1283-91

PM: PUBMED 17484756


PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cholinesterase Inhibitors [administration & dosage] [therapeutic use]; Cognition Disorders [diagnosis] [drug therapy]; Cross-Over Studies; Dose-Response Relationship, Drug; Double-Blind Method; Epilepsy [diagnosis] [drug therapy] [psychology]; Health Status; Indans [therapeutic use]; Memory Disorders [drug therapy] [psychology]; Neuropsychological Tests; Piperidines [therapeutic use]; Placebos; Quality of Life; Severity of Illness Index; Social Adjustment; Treatment Outcome; Humans[checkword]

CC: SR-DEMENTIA: SR-EPILEPSY

AB: **PURPOSE:** To determine whether an acetylcholinesterase inhibitor, such as donepezil, would improve memory or other cognitive/psychological functions in epilepsy patients with subjective memory complaints. **METHODS:** Twenty-three epilepsy patients with subjective memory difficulty were randomized to either 3 months of donepezil (10 mg/day) or 3 months of placebo treatment, and then crossed over to the other treatment arm. Patients and physicians were blinded to treatment phase throughout data acquisition. Assessment of memory and other cognitive functions, subjective memory, mood, and self-rated quality of life (QOL) and social functioning was performed at baseline and following completion of both treatment phases. Seizure frequency and severity as well as treatment emergent adverse effects were also monitored. **RESULTS:** Donepezil treatment was not associated with improvement in memory or other cognitive functions, mood, social functioning or QOL. Comparable increases in self-rated memory functioning relative to baseline were evident during donepezil and placebo phases. Donepezil treatment was not associated with increased seizure frequency or severity. Similar to group results, analysis of change within individual patients as a function of treatment phase also showed neither significant benefit nor detriment associated with donepezil. **CONCLUSION:** This study found no benefit on memory or other cognitive/psychological functions in a heterogeneous group of epilepsy patients with subjective memory difficulty. Further investigation would be required to determine whether individual patients, or those with particular epilepsy syndromes, might benefit from donepezil or other acetylcholinesterase inhibitors, or if a higher dosage might be effective.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/630/CN-00588630/frame.html>

Record #346 of 370 

ID: CN-00700024

AU: Bruera E

AU: Osta B

AU: Valero V

AU: Driver LC

AU: Pei BL

AU: Shen L

AU: Poulter VA

AU: Palmer JL

TI: Donepezil for cancer fatigue: a double-blind, randomized, placebo-controlled trial.

SO: Journal of clinical oncology

YR: 2007

VL: 25

NO: 23

PG: 3475-81

PM: PUBMED 17687152

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural

KY: Disease Progression; Double-Blind Method; Fatigue [drug therapy]; Indans [therapeutic use]; Neoplasms [complications]; Nootropic Agents [therapeutic use]; Piperidines [therapeutic use]; Placebos; Telemedicine; Time Factors; Treatment Outcome; Aged[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]; Middle Aged[checkword]

CC: SR-COMMUN: SR-SYMPT

DOI: 10.1200/JCO.2007.10.9231

AB: PURPOSE: To evaluate the effectiveness of donepezil compared with placebo in cancer patients with fatigue as measured by the Functional Assessment for Chronic Illness Therapy-Fatigue (FACIT-F). PATIENTS AND METHODS: Patients with fatigue score ≥ 4 on a scale of 0 to 10 (0 = no fatigue, 10 = worst possible fatigue) for more than 1 week were included. Patients were randomly assigned to receive donepezil 5 mg or placebo orally every morning for 7 days. A research nurse contacted the patients by telephone daily to assess toxicity and fatigue level. All patients were offered open-label donepezil during the second week. FACIT-F and/or the Edmonton Symptom Assessment System (ESAS) were assessed at baseline, and days 8, 11, and 15. The FACIT-F fatigue subscale score on day 8 was considered the primary end point. RESULTS: Of 142 patients randomly assigned to treatment, 47 patients in the donepezil group and 56 in the placebo group were assessable for final analysis. Fatigue intensity improved significantly on day 8 in both donepezil and placebo groups. However, there was no significant difference in fatigue improvement by FACIT-F ($P = .57$) or ESAS ($P = .18$) between groups. In the open-label phase, fatigue intensity continued to be low as compared with baseline. No significant toxicities were observed. CONCLUSION: Donepezil was not significantly superior to placebo in the treatment of cancer-related fatigue.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/024/CN-00700024/frame.html>

Record #347 of 370



ID: CN-00578157

AU: Fagerlund B

AU: Sørholm B

AU: Fink-Jensen A

AU: Lublin H

AU: Glenthøj BY

TI: Effects of donepezil adjunctive treatment to ziprasidone on cognitive deficits in schizophrenia: a double-blind, placebo-controlled study.

SO: Clinical neuropharmacology

YR: 2007

VL: 30

NO: 1

PG: 3-12

PM: PUBMED 17272964

PT: Journal Article; Randomized Controlled Trial

KY: Antipsychotic Agents [administration & dosage]; Basal Ganglia Diseases [chemically induced]; Cholinesterase Inhibitors [administration & dosage]; Cognition Disorders [drug therapy] [etiology]; Double-Blind Method; Drug Therapy, Combination; Indans [administration & dosage] [adverse effects]; Piperazines [administration & dosage]; Piperidines [administration & dosage] [adverse effects]; Schizophrenia [complications]; Thiazoles [administration & dosage]; Treatment Outcome; Adult[checkword]; Female[checkword]; Humans[checkword]; Male[checkword]

CC: SR-DEMENTIA: SR-SCHIZ

DOI: 10.1097/01.WNF.0000240940.67241.F6

AB: The objective of this study was to examine the effects of adjunctive treatment with the acetylcholinesterase inhibitor, donepezil, on cognitive deficits and psychopathology in schizophrenic patients treated with the antipsychotic, ziprasidone. The design of the study was double blind, placebo controlled, and longitudinal. Patients were treated with ziprasidone for 8 weeks, thereafter randomized to 4 months of double-blind adjunctive treatment with either donepezil (dose, 5-10 mg) or placebo. The severity of psychopathology (PANSS) and the cognitive deficits were examined at baseline and after 4 months. A total of 21 schizophrenic patients were enrolled, of whom 11 patients completed the trial (donepezil, n = 7; placebo, n =

4). There were no within- or between-group differences in changes on the Positive and Negative Syndrome Scale scores or a global cognitive score. Within-group improvements (all at trend level $P = 0.07$) were seen in the placebo group on Trail-Making Test B, immediate verbal recall, and set-shifting errors. The donepezil group showed a significant deterioration on planning efficiency ($P = 0.04$). Between-group differences were found between the lack of improvement in immediate verbal recall in the donepezil group and the improvement in the placebo group ($P = 0.02$), and between the deterioration of planning efficiency in the donepezil group and the stability in the placebo group (trend level, $P = 0.07$). Linear regression analyses showed that neither baseline psychopathology scores, baseline levels of cognitive deficits, nor psychopathology changes over time accounted for these changes in cognitive scores. The study found no evidence of improved cognition after treatment with donepezil, although the conclusions that can be drawn are limited by the small sample size.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/157/CN-00578157/frame.html>

Record #348 of 370



ID: CN-00629564

AU: Devi G

AU: Massimi S

AU: Schultz S

AU: Khosrowshahi L

AU: Laakso UK

TI: A double-blind, placebo-controlled trial of donepezil for the treatment of menopause-related cognitive loss.

SO: Gender medicine

YR: 2007

VL: 4

NO: 4

PG: 352-8

PM: PUBMED 18215726

PT: Journal Article; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Cholinesterase Inhibitors [therapeutic use];Cognition Disorders [drug therapy] [etiology];Double-Blind Method;Indans [therapeutic use];Memory Disorders [drug therapy] [etiology];Menopause [physiology] [psychology];Piperidines [therapeutic use];Treatment Outcome;Female[checkword];Humans[checkword];Middle Aged[checkword]

CC: SR-MENSTR

AB: BACKGROUND: Perimenopausal and menopausal women are more likely to complain of memory loss than are premenopausal women, although the association between menopause and cognitive loss remains controversial. Recently published studies on the risks of hormone therapy have left many women and their physicians seeking effective nonhormonal treatments for menopausal symptoms, including cognitive loss. OBJECTIVE: This study investigated the efficacy of the cholinesterase agent donepezil in the treatment of menopause-related cognitive loss. METHODS: Community-dwelling women in natural menopause were recruited for a randomized, double-blind, placebo-controlled study of donepezil. To qualify for enrollment, the Brief Cognitive Rating Scale was used to determine cognitive symptoms, and women with depression were excluded. Subjects were randomized to receive either donepezil, commencing at 5 mg/d, or placebo. At week 6 of randomization, the dosage of donepezil was increased to 10 mg/d. Treatment continued throughout the 26-week study. The primary outcome measure was the overall change in neurocognitive test results over time. Outcome variables of test scores were analyzed before and after receipt of donepezil or placebo. RESULTS: A total of 28 women aged 46 to 60 years were enrolled. Fourteen women were randomized to receive active drug, 14 to placebo. Two women dropped out of the placebo group. There were no statistically significant differences between treatment groups in post-/pre-dose mean score ratios. No interactions were statistically significant. The P values for tests of equal variances did not reveal a difference in the means. Subjective measures did show some trends toward improvement in memory and cognition. CONCLUSION: Donepezil was no more effective than placebo in treating the symptoms of menopause- related memory and cognitive loss.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/564/CN-00629564/frame.html>

Record #349 of 370



ID: CN-00577480

AU: Mendez MF

AU: Shapira JS

AU: McMurtray A

AU: Licht E

TI: Preliminary findings: behavioral worsening on donepezil in patients with frontotemporal dementia.

SO: American journal of geriatric psychiatry

YR: 2007

VL: 15

NO: 1

PG: 84-7

PM: PUBMED 17194818

PT: Controlled Clinical Trial; Journal Article; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Behavioral Symptoms [chemically induced];Cholinesterase Inhibitors [adverse effects];Compulsive Behavior [chemically induced];Dementia [drug therapy];Indans [adverse effects];Piperidines [adverse effects];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1097/01.JGP.0000231744.69631.33

AB: OBJECTIVE: The objective of this study was to evaluate donepezil, an acetylcholinesterase inhibitor, in the treatment of frontotemporal dementia (FTD). METHODS: Twelve patients with FTD who received donepezil for six months were compared with 12 FTD controls on behavioral measures. RESULTS: The groups did not differ on most variables at baseline or at six months; however, the donepezil group had greater worsening on the FTD Inventory. Four treated patients had increased disinhibited or compulsive acts, which abated with discontinuation of the medication. CONCLUSION: There were no changes in global cognitive performance or dementia severity; however, a subgroup of patients with FTD can experience worsening of symptoms with donepezil.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/480/CN-00577480/frame.html>

Record #350 of 370



ID: CN-00697367

AU: Kohler CG

AU: Martin EA

AU: Kujawski E

AU: Bilker W

AU: Gur RE

AU: Gur RC

TI: No effect of donepezil on neurocognition and social cognition in young persons with stable schizophrenia.

SO: Cognitive neuropsychiatry

YR: 2007

VL: 12

NO: 5

PG: 412-21

PM: PUBMED 17690999

PT: Journal Article; Randomized Controlled Trial

KY: Brain [drug effects];Brief Psychiatric Rating Scale;Cholinesterase Inhibitors [pharmacology] [therapeutic use];Cognition Disorders [diagnosis] [drug therapy] [etiology];Diagnostic and Statistical Manual of Mental Disorders;Indans [pharmacology] [therapeutic use];Neuropsychological Tests;Piperidines [pharmacology] [therapeutic use];Schizophrenia [complications] [diagnosis];Severity of Illness Index;Social Perception;Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-SCHIZ

DOI: 10.1080/13546800701307263

AB: INTRODUCTION: Cognitive dysfunction is common in schizophrenia and linked with psychosocial dysfunction. We examined the possible effect of a 16-week trial of donepezil on cognition in young persons with stable schizophrenia. METHOD: Twenty-six outpatients who met criteria for age, duration of illness, clinical stability, and medications were randomly assigned to 16-week treatment with donepezil or placebo using a double blind design. At beginning and conclusion of the trial, participants completed standardised computerised assessment of neurocognition and social cognition. Symptomatology and functioning were assessed using standard rating scales for negative and positive symptoms, depression and mania, and quality of life. RESULTS: No treatment effects were found on any cognitive functions or clinical symptoms in placebo or donepezil groups. CONCLUSION: Similar to other studies using acetylcholinesterase inhibitors in more heterogeneous and symptomatic groups of patients with schizophrenia, donepezil does not appear to enhance cognitive abilities. Persistent cognitive impairment in schizophrenia with pervasive effects on psychosocial functioning and outcome, urge the search for agents that may offer improvement.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/367/CN-00697367/frame.html>

Record #351 of 370



ID: CN-00577471

AU: Rowan E

AU: McKeith IG

AU: Saxby BK

AU: O'Brien JT

AU: Burn D

AU: Mosimann U

AU: Newby J

AU: Daniel S

AU: Sanders J

AU: Wesnes K

TI: Effects of donepezil on central processing speed and attentional measures in Parkinson's disease with dementia and dementia with Lewy bodies.

SO: Dementia and geriatric cognitive disorders

YR: 2007

VL: 23

NO: 3

PG: 161-7

PM: PUBMED 17192712

PT: Comparative Study; Controlled Clinical Trial; Journal Article; Multicenter Study; Research Support, Non-U.S. Gov't


KY: Attention [drug effects];Chi-Square Distribution;Cholinesterase Inhibitors [therapeutic use];Cognition [drug effects];Dementia [complications] [drug therapy];Indans [therapeutic use];Lewy Body Disease [complications] [drug therapy];Mental Processes [drug effects];Nootropic Agents [therapeutic use];Parkinson Disease [complications] [drug

therapy];Piperidines [therapeutic use];Reaction Time [drug effects];Reference Values;Statistics, Nonparametric;Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

DOI: 10.1159/000098335

AB: BACKGROUND: We examined attention-enhancing effects of the cholinesterase inhibitor donepezil in Dementia with Lewy bodies (DLB) and Parkinson's disease with dementia (PDD) by means of open label study. METHODS: 22 DLBs and 23 PDDs were assessed over 20 weeks using the Cognitive Drug Research Computerized Attentional Tasks. We examined how much closer our patients moved towards being normal for their age by comparing them to a non-demented elderly control sample (n = 183, aged 71-75 years). RESULTS: Donepezil treatment improved power of attention, continuity of attention and reaction time variability. The deficit in responses was moved towards normal by 38 and 56% for power of attention and 22 and 10% for continuity of attention in PDD and DLB, respectively. CONCLUSIONS: Improvements in attention were found with donepezil in PDD and DLB.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/471/CN-00577471/frame.html>

Record #352 of 370 

ID: CN-00724797


TI: Double-blind, parallel-group comparison of 23 mg donepezil sustained release (sr) to 10 mg donepezil immediate release (ir) in patients with moderate to severe Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/797/CN-00724797/frame.html>

Record #353 of 370 

ID: CN-00621798

AU: Sun YZ

AU: Zhu PY

AU: Zhang M

AU: Zhang Y

TI: [Clinical observation on Yuanluo Tongjing needling method for treatment of mild cognitive impairment].

SO: Zhongguo zhen jiu [Chinese acupuncture & moxibustion]

YR: 2007

VL: 27

NO: 11

PG: 810-2

PM: PUBMED 18085142

PT: English Abstract; Journal Article; Randomized Controlled Trial

KY: Acupuncture Therapy [methods];Cognition Disorders [therapy];Medicine, Chinese Traditional;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

CC: SR-BEHAV: SR-COMPMED

AB: OBJECTIVE: To observe therapeutic effect of Yuanluo Tongjing needling method for treatment of mild cognitive impairment and search for an effective therapy of TCM for mild cognitive impairment. METHODS: Sixty cases were randomly divided into an observation group and a control group, 30 cases in each group. The observation group were treated by Yuanluo Tongjing needling method with Baihui (GV 20), Danzhong (CV 17), Guanyuan (CV 4), Shenmen (HT 7), etc. selected, and the control group by oral administration of Aricept, 2.5 mg. Changes of scores of all indexes in clinical memory scale and memory quotient (MQ) before and after treatment were investigated in the two groups, and clinical therapeutic effects were assessed by using MQ increasing values. RESULTS: After treatment for 30 days, the scores of memory quotient, direction memory, picture free memory, re-cognition of no-significant picture forms and associated memory of human picture characteristics significantly increased ($P < 0.01$, $P < 0.05$) in the observation group; and all the indexes except associated memory in the control group significantly changed ($P < 0.05$), with no significant difference between the two groups ($P > 0.05$). The good rate for memory effect was 80.0% in the observation group and 76.7% in the control group with no significant difference between the two groups ($P > 0.05$). CONCLUSION: Yuanluo Tongjing needling method can improve memory ability of the patient of mild cognitive impairment.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/798/CN-00621798/frame.html>

Record #354 of 370



ID: CN-00724754

AU: Anon

TI: A randomised, double-blind, double-dummy, oral donepezil controlled study on the safety and efficacy of repeated monthly subcutaneous injections of a sustained-release implant of zt 1 in patients with moderate Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/754/CN-00724754/frame.html>

Record #355 of 370



ID: CN-00689973

AU: Ohn SH

AU: Park YH

TI: Effect of donepezil on the reorganization of cognitive neural network in patients with post-stroke cognitive impairment

SO: ClinicalTrials.gov

YR: 2007

CC: SR-STROKE

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/973/CN-00689973/frame.html>

Record #356 of 370



ID: CN-00857000

AU: Howard RJ

AU: Juszczak E

AU: Ballard CG

AU: Bentham P Brown RG

AU: Bullock R

AU: Burns AS

TI: Donepezil for the treatment of agitation in Alzheimer's disease

SO: New England journal of medicine

YR: 2007


VL: 357

NO: 14

PG: 1382-92

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/000/CN-00857000/frame.html>

Record #357 of 370 

ID: CN-00714048

AU: Howard RJ [Principal Investigator]

TI: Donepezil and memantine in moderate to severe Alzheimer's disease

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/048/CN-00714048/frame.html>

Record #358 of 370



ID: CN-00714097

AU: Anon

TI: Memantine versus donepezil in mild to moderate Alzheimer's disease a randomized trial with magnetic resonance spectroscopy

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/097/CN-00714097/frame.html>

Record #359 of 370



ID: CN-00724799

AU: Tinklenberg JR

AU: Kraemer HC

AU: Yaffe K

AU: Ross L

AU: Sheikh J

AU: Ashford JW

AU: Yesavage JA

AU: Taylor JL

TI: Donepezil treatment and alzheimer disease: can the results of randomized clinical trials be applied to alzheimer disease patients in clinical practice?

SO: American journal of geriatric psychiatry

YR: 2007

VL: 15

NO: 11

PG: 953-60

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/799/CN-00724799/frame.html>

Record #360 of 370



ID: CN-00617482

AU: Rockwood K

AU: Black S

AU: Bedard MA

AU: Tran T

AU: Lussier I

TI: Specific symptomatic changes following donepezil treatment of Alzheimer's disease: a multi-centre, primary care, open-label study.

SO: International journal of geriatric psychiatry

YR: 2007

VL: 22

NO: 4

PG: 312-9

PM: PUBMED 17006874

PT: Journal Article; Multicenter Study; Randomized Controlled Trial; Research Support, Non-U.S. Gov't

KY: Activities of Daily Living [classification] [psychology];Alzheimer Disease [diagnosis] [drug therapy] [psychology];Attention [drug effects];Caregivers [psychology];Cost of Illness;Follow-Up Studies;Indans [adverse effects] [therapeutic use];Mental Recall [drug effects];Mental Status Schedule;Motivation;Nootropic Agents [adverse effects] [therapeutic use];Orientation [drug effects];Piperidines [adverse effects] [therapeutic use];Primary Health Care;Stereotyped Behavior [drug effects];Treatment Outcome;Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1002/gps.1675

AB: BACKGROUND: Standard measurement scales used in anti-dementia trials may not capture symptomatic changes recognized by clinicians and caregivers. We studied a symptom checklist, completed separately by caregivers and by clinicians, to identify patterns of change associated with donepezil treatment. METHODS: In a multi-centre, 6-month, open-label study of 101 primary care patients, changes in a 19-symptom checklist were assessed in relation to changes in standardized scales of cognition, activities of daily living, behavior, and caregiver burden. RESULTS: Three symptoms were reported in more than 80% of patients by both clinicians and caregivers: problems in remembering, (97%), temporal orientation (89%), and repetitiveness (85%). Five others overlapped on each of the clinician and caregiver 'top ten', including cognitive activation, spatial orientation, leisure, attention, and apathy. Clinicians reported that symptoms did not improve in 38 patients, whereas there was some improvement in 43, and improvement in most symptoms in 20. Caregivers reported that symptoms did not improve in 55 patients, whereas 27 and 19 patients showed some and most symptoms improving respectively. Patients with the greatest symptomatic improvement also improved most on the ADAS-Cog and the other standardized measures, whereas no improvement (or decline) in each standardized measure was observed in people whose symptoms worsened or did not improve. CONCLUSION: A symptom checklist allowed clinically meaningful profiles to be identified, but revealed different estimates of response between clinicians and caregivers. Both agreed that improved executive function was the most common response. A symptom checklist can help translate between standard measures and everyday practice.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/482/CN-00617482/frame.html>

Record #361 of 370



ID: CN-00625501

AU: Bruera E

AU: Osta B

AU: Valero V

AU: Driver L

AU: Palmer J

AU: Pei B

AU: Shen L

AU: Poulter V

TI: Donepezil for cancer-related fatigue: A double-blind, randomized, placebo-controlled study [abstract]

SO: Journal of Clinical Oncology : ASCO annual meeting proceedings

YR: 2007


VL: 25

NO: 18S Part I

PG: 493

CC: HS-HAEMATOL: SR-HAEMATOL: SR-SYMPT: HS-HANDSRCH

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/501/CN-00625501/frame.html>

Record #362 of 370 

ID: CN-00714341

AU: Anon


TI: [Public title] BOLD functional magnetic resonance imaging (fMRI) and cerebral blood flow measurements as biomarkers for cognition enhancing drugs; [Scientific title] A 4-period, placebo-controlled, crossover study to evaluate the utility and feasibility of BOLD fMRI and cerebral blood flow measurements as biomarkers for cognition enhancing drugs (donepezil and MK3134)

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/341/CN-00714341/frame.html>

Record #363 of 370 

ID: CN-00702233

AU: Ollat H

AU: Laurent B

AU: Bakchine S

AU: Michel BF

AU: Touchon J

AU: Dubois B

TI: [Effects of the association of sulbutiamine with an acetylcholinesterase inhibitor in early stage and moderate Alzheimer disease].

SO: L'Encéphale

YR: 2007

VL: 33

NO: 2

PG: 211-5

PM: PUBMED 17675917

PT: English Abstract; Journal Article; Multicenter Study; Randomized Controlled Trial

KY: Alzheimer Disease [drug therapy];Attention [drug effects];Brain [drug effects];Cholinesterase Inhibitors [pharmacology] [therapeutic use];Drug Therapy, Combination;Hippocampus [drug effects];Indans [pharmacology] [therapeutic use];Piperidines [pharmacology] [therapeutic use];Prefrontal Cortex [drug effects];Severity of Illness Index;Thiamine [analogs & derivatives] [pharmacology] [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword];Middle Aged[checkword]

AB: The efficacy of the inhibitors of acetylcholinesterase in Alzheimer's Disease (AD) is moderated and some patients do not respond to these treatments. Sulbutiamine potentializes cholinergic and glutamatergic transmissions, mainly in hippocampus and prefrontal cortex. This multicentric, randomized and double-blind trial evaluates the effects of the association of sulbutiamine to an anticholinesterasic drug in cognitive functions in patients with AD at an early stage (episodic memory, working memory, executive functions, attention). Patients had first donepezil (D) or sulbutiamine (S) during three months. During this period, only attention improved in both groups. During the three following months, a placebo (P) in patients D and donepezil in patients S were added. Compared to entry results, episodic memory decreased in group D + P but improved in group S + D. At the same time the improvement of attention persisted in both groups. Daylife activities only improved in group S + D. In conclusion sulbutiamine can be an adjuvant to treatment in early stage and moderate AD by anticholinesterasic drugs.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/233/CN-00702233/frame.html>

Record #364 of 370



ID: CN-00713964

AU: Ritchie C

TI: A phase III, seven-day randomised, double-blind, placebo-controlled, parallel group study to assess efficacy of Donepezil for reducing the incidence and severity of Post-Operative Delirium after an elective total hip or knee replacement in patients over 65 years old

SO: ISRCTN Regsiter [<http://www.controlled-trials.com>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/964/CN-00713964/frame.html>

Record #365 of 370



ID: CN-00589776

AU: Baewert A

AU: Gombas W

AU: Schindler SD

AU: Peterzell-Moelzer A

AU: Eder H

AU: Jagsch R

AU: Fischer G

TI: Influence of peak and trough levels of opioid maintenance therapy on driving aptitude.

SO: European addiction research

YR: 2007

VL: 13

NO: 3

PG: 127-35

PM: PUBMED 17570908

PT: Comparative Study; Controlled Clinical Trial; Journal Article

KY: Attention [drug effects];Austria;Automobile Driving [psychology];Buprenorphine [administration & dosage] [adverse effects] [pharmacokinetics];Decision Making [drug effects];Metabolic Clearance Rate;Methadone [administration & dosage] [adverse effects] [pharmacokinetics];Narcotics [administration & dosage] [pharmacokinetics];Neuropsychological Tests;Opioid-Related Disorders [rehabilitation];Prospective Studies;Reaction Time [drug effects];Adult[checkword];Female[checkword];Humans[checkword];Male[checkword]

CC: SR-ADDICTN

DOI: 10.1159/000101548

AB: To evaluate driving aptitude and traffic-relevant performance at peak and trough medication levels in opioid-dependent patients receiving maintenance therapy with either buprenorphine (mean: 13.4 mg) or methadone (52.7 mg) and a medication-free control group, the Addiction Clinic at Medical University Vienna conducted a prospective, open-label trial where 40 opioid-dependent patients maintained either on buprenorphine or methadone were assessed regarding their traffic-relevant performance. Using the standardized Act and React Testsystem (ART) 2020 Standard test battery, traffic-relevant performance was analysed 1.5 h (peak level) and 20 h (trough level) after administration of opioid maintenance therapy. Results showed that patients at trough level had a significantly higher percentage of incorrect reactions ($p = 0.03$) and more simple errors ($p = 0.02$) than patients at peak level as well as methadone-maintained patients at peak level tended to perform less well than buprenorphine-maintained patients in some of the test items, e.g. methadone-maintained patients at trough level had a higher number of delayed reactions in the RST3 phase 2 test ($p = 0.09$) and answered fewer questions correctly in the visual structuring ability test ($p = 0.04$). This investigation indicates that opioid-maintained patients did not differ significantly at peak vs. trough level in the majority of the investigated items and that both substances do not appear to affect traffic-relevant performance dimensions when given as a maintenance therapy in a population where concomitant consumption would be excluded.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/776/CN-00589776/frame.html>

Record #366 of 370



ID: CN-00714005

AU: Anon


TI: Double-blind study of e2020 in patients with dementia with Lewy bodies - phase II

SO: ClinicalTrials.gov [<http://clinicaltrials.gov>]

YR: 2007

CC: SR-DEMENTIA

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/005/CN-00714005/frame.html>

Record #367 of 370 

ID: CN-00574892

AU: DeCarli C

AU: Frisoni GB

AU: Clark CM

AU: Harvey D

AU: Grundman M

AU: Petersen RC

AU: Thal LJ

AU: Jin S

AU: Jack CR

AU: Scheltens P

TI: Qualitative estimates of medial temporal atrophy as a predictor of progression from mild cognitive impairment to dementia.

SO: Archives of neurology

YR: 2007

VL: 64

NO: 1

PG: 108-15

PM: PUBMED 17210817

PT: Comparative Study; Evaluation Studies; Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't

KY: Atrophy [pathology] [prevention & control];Cognition Disorders [complications] [drug therapy] [pathology];Dementia [etiology] [pathology] [prevention & control];Disease Progression;Double-Blind Method;Indans [therapeutic use];Kaplan-Meier Estimate;Magnetic Resonance Imaging [methods];Neuropsychological Tests;Nootropic Agents [therapeutic use];Piperidines [therapeutic use];Predictive Value of Tests;Reproducibility of Results;Temporal Lobe [drug effects] [pathology];Vitamin E [administration & dosage];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1001/archneur.64.1.108

AB: BACKGROUND: Individuals diagnosed as having mild cognitive impairment (MCI) have a high likelihood of progressing to dementia within 3 to 5 years, but not all individuals with MCI progress to dementia. Prognostic uncertainty suggests the need for additional measures to assist the clinician. OBJECTIVE: To assess the added value of qualitative measures of medial temporal atrophy (MTA) to estimate the relative risk of progressing from MCI to dementia. DESIGN: A 3-year, double-blind, placebo-controlled Alzheimer's Disease Cooperative Study initially designed to evaluate the efficacy of donepezil hydrochloride or vitamin E vs placebo to delay progression of MCI to dementia. SETTING: Memory assessment centers. PATIENTS: A total of 190 individuals with MCI. MAIN OUTCOME MEASURES: Ratings of MTA performed using magnetic resonance images obtained at baseline. Log-rank tests and Cox proportional hazards ratios examining the significance of MTA estimates in predicting progression of MCI to dementia. RESULTS: A mean MTA score greater than 2.0 was associated with a greater than 2-fold increased likelihood of progression to dementia during the observation period (hazards ratio, 2.30; 95% confidence interval, 1.09-4.92; P = .03) after controlling for age, education, sex, and baseline Mini-Mental State Examination score. CONCLUSIONS: Adjusted estimates of MTA were associated with significantly increased risk of developing dementia within 3 years, suggesting that obtaining a magnetic resonance image during the evaluation of MCI may offer additional independent information about the risk of progression to dementia. Given the relatively high prevalence of MCI in the general population, use of this method as part of routine clinical evaluation may help identify individuals who might benefit from increased surveillance and future treatment. TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00000173.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/892/CN-00574892/frame.html>

Record #368 of 370



ID: CN-00586802

AU: Fleisher AS

AU: Sowell BB

AU: Taylor C

AU: Gamst AC

AU: Petersen RC

AU: Thal LJ

TI: Clinical predictors of progression to Alzheimer disease in amnestic mild cognitive impairment.

SO: Neurology

YR: 2007

VL: 68

NO: 19

PG: 1588-95

PM: PUBMED 17287448

PT: Journal Article; Randomized Controlled Trial; Research Support, N.I.H., Extramural; Research Support, Non-U.S. Gov't; Validation Studies

KY: Age Distribution;Alzheimer Disease [diagnosis] [drug therapy] [psychology];Amnesia [diagnosis] [drug therapy] [psychology];Antioxidants [therapeutic use];Apolipoprotein E4 [genetics];Cholinesterase Inhibitors [therapeutic use];Cognition Disorders [diagnosis] [drug therapy] [psychology];Cohort Studies;Disease Progression;Genotype;Indans [therapeutic use];Linear Models;Neuropsychological Tests [standards] [statistics & numerical data];Piperidines [therapeutic use];Placebo Effect;Predictive Value of Tests;Prognosis;Sex Distribution;Vitamin E [therapeutic use];Aged[checkword];Aged, 80 and over[checkword];Female[checkword];Humans[checkword];Male[checkword]

DOI: 10.1212/01.wnl.0000258542.58725.4c

AB: OBJECTIVE: To investigate the neurocognitive measures that best predict progression from amnestic mild cognitive impairment (aMCI) to Alzheimer disease (AD). METHODS: We evaluated 539 participants with aMCI from the Alzheimer's Disease Cooperative Study clinical drug trial of donepezil, vitamin E, or placebo. During the study period of 36 months, 212 aMCI participants progressed to AD. Using progression from aMCI to AD within 36 months as the dependent variable, a generalized linear model was fit to the data using the least absolute shrinkage and selection operator. Independent variables included in this analysis were age, sex, education, APOE-e4 (APOE4) status, family history of dementia, Mini-Mental State Examination score, Digits Backwards (Wechsler Memory Scale), Maze Time and Errors, Number Cancellation, Delayed Recall of Alzheimer's Disease Assessment Scale Word List, New York University Paragraph Recall Test (Immediate and Delayed), Boston Naming Test, Category Fluency, Clock Drawing Test, and the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-cog). RESULTS: The model that best predicted progression from aMCI to AD over 36

months included APOE4 status, the Symbol Digit Modalities Test, Delayed 10-Word List Recall, New York University Paragraph Recall Test (Delayed), and the ADAS-cog total score. When APOE4 was removed from the analysis the resulting model had a similar estimated predictive accuracy as the full model. As determined by cross-validation, the estimated predictive accuracy of the final model was 80%. CONCLUSION: Progression from amnesic mild cognitive impairment to Alzheimer disease in this cohort was best determined by combining four common, easily administered, cognitive measures.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/802/CN-00586802/frame.html>

Record #369 of 370



ID: CN-00849141

AU: Struve Maren

AU: Moayer M

AU: Diesch E

AU: Flor H

TI: Extinction training for tinnitus: first results

SO: 2nd International TRI Tinnitus Conference 2007, Monte Carlo, Monaco, July 17-21 2007

YR: 2007

PG: 97-8

CC: SR-ENT

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/141/CN-00849141/frame.html>

Record #370 of 370



ID: CN-00642136

AU: Ahmed S

AU: Choudhary J

AU: Ahmed M

AU: Arora V

AU: Parul

AU: Ali S

TI: Treatment of ventilator-associated pneumonia with piperacillin-tazobactam and amikacin vs cefepime and levofloxacin: A randomized prospective study.

SO: Indian journal of critical care medicine

YR: 2007

VL: 11

NO: 3

PG: 117-21

XR: EMBASE 2007491948

PT: Journal: Article

KY: adult // antibiotic therapy // APACHE // article // artificial ventilation // clinical trial // controlled clinical trial // controlled study // drug cost // female // hospital admission // hospitalization // human // intensive care unit // major clinical study // male // mortality // observational study // prospective study // randomized controlled trial // treatment outcome // *ventilator associated pneumonia/dt [Drug Therapy] // *ventilator associated pneumonia/et [Etiology] // *amikacin/cb [Drug Combination] // *amikacin/cm [Drug Comparison] // *amikacin/dt [Drug Therapy] // antibiotic agent/dt [Drug Therapy] // *cefepime/cb [Drug Combination] // *cefepime/cm [Drug Comparison] // *cefepime/dt [Drug Therapy] // *levofloxacin/cb [Drug Combination] // *levofloxacin/cm [Drug Comparison] // *levofloxacin/dt [Drug Therapy] // *piperacillin plus tazobactam/cb [Drug Combination] // *piperacillin plus tazobactam/cm [Drug Comparison] // *piperacillin plus tazobactam/dt [Drug Therapy]

CC: HS-SASIANCC: HS-HANDSRCH

AB: Study Objectives: To compare the survival benefits and cost effectiveness of cefepime-levofloxacin (C-L) as an alternative empirical antibiotic therapy for ventilator associated pneumonia (VAP) with the most widely recommended combination of piperacillin-tazobactam and amikacin (P-T-A). Design: Prospective, observational, cohort study. Materials and Methods: A total number of 879 patients were admitted in the ICU during 1st April 2004 to 31st March 2005 and were screened for the study. Ninety-three patients were clinically suspected to develop early onset VAP. The patients were randomly divided into two groups receiving Cefepime-Levofloxacin (C-L) or Piperacillin-Tazobactam-Amikacin (P-T-A) as empirical antibiotic therapy. Treatment outcome was compared between the groups, which included ICU mortality, duration of mechanical ventilation, duration of ICU stay and total cost incurred on antibiotics. Results: The epidemiological characteristics including mean age and APACHE II score were comparable between the two groups. The mortality rates in the two

groups were similar. The duration of mechanical ventilation was shorter in C-L group (5-8 days) as compared to P-T-A group (6-11 days). Also, the mean duration of ICU stay was reduced in C-L group (16+2.1 days) as compared to P-T-A group (19+3.4 days). Further, the overall cost of antibiotics in C-L group was $\frac{1}{3}$ of the cost in P-T-A group. Eleven patients were found to be receiving inappropriate antibiotics and seven patients developed ARF during the course of antibiotic therapy. These patients were excluded from the study. Conclusion: Cefepime-Levofloxacin combination is an effective alternative to piperacillin-tazobactam-amikacin for empirical treatment of VAP. It reduces the duration of mechanical ventilation, number of days of ICU stay and overall cost of antibiotics.

US: <http://onlinelibrary.wiley.com/o/cochrane/clcentral/articles/136/CN-00642136/frame.html>