30633223\_PD.txt

Title: A randomized controlled trial of neuromuscular electrical stimulation for chronic urinary retention following traumatic brain injury.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/22 06:00 [medline]

BACKGROUND: This study aimed to evaluate the effectiveness of neuromuscular electrical stimulation (NMES) therapy for chronic urinary retention (CUR) following traumatic brain injury (TBI). METHODS: This 2-arm randomized controlled trial (RCT) enrolled 86 eligible patients with CUR following TBI. All included patients were randomly allocated to a treatment group (n = 43) or a sham group (n = 43). The administration of NMES or sham NMES, as intervention, was performed for an 8-week period treatment, and 4-week period follow-up. In addition, all subjects were required to undergo indwelling urinary catheter throughout the study period. The primary outcome was assessed by the <P 0> post-voiding residual urine volume (PV-VRU) </>. The secondary outcomes were evaluated by the <P 0> voided volume </>, <P 0> maximum urinary flow </> rate (Qmax), and <P 30> quality of life </>, as assessed by [T Barthel Index (BI)] scale. In addition, <P 38> adverse events </> were also recorded during the study period. All primary and secondary outcomes were measured at baseline, at the end of 8-week treatment, and 4-week follow-up. RESULTS: At the end of 8-week treatment, the patients in the treatment group did not achieve better outcomes in <P 0> post-voiding residual urine volume (PV-VRU) </> (P = .66), <P 0> voided volume </> (P = .59), <P 0> maximum urinary flow </> rate (Qmax) (P = .53), and [T Barthel Index (BI)] scores (P = .67), than patients in the control group. At the end of 4-week follow-up, there were also no significant differences regarding the <P 0> post-voiding residual urine volume (PV-VRU) </> (P = .42), <P 0> voided volume </> (P = .71), <P 0> maximum urinary flow </> rate (Qmax) (P = .24), and [T Barthel Index (BI)] scores (P = .75) between 2 groups. No <P 38> adverse events </> occurred in either group. CONCLUSIONS: In summary, the findings of this study showed that NMES therapy may not benefit patients with CUR following TBI.

*30633722\_PD.txt*

*Title: A Fully Automated Method for the Determination of Serum Belatacept and Its Application in a Pharmacokinetic Investigation in Renal Transplant Recipients.*

*Publication Type: Randomized Controlled Trial*

*Journal-Name:Therapeutic drug monitoring*

*Journal ID: 7909660*

*Publication date: 2019/02/15 06:00 [medline]*

*BACKGROUND: Belatacept (Nulojix; Bristol-Myers Squibb, New York, NY) is a biological immunosuppressive drug used for the prophylaxis of acute rejection after renal transplantation. Few studies have described belatacept pharmacokinetics, and the effect of therapeutic drug monitoring has not been investigated. We have developed a drug-capture assay (using drug target) to measure belatacept in serum and applied this assay in a pharmacokinetic study in renal transplant recipients. METHODS: CD80 was used to trap belatacept onto streptavidin-coated wells. Captured drug was quantified using Eu-labeled protein A and time-resolved fluorescence. The assay was applied in a pilot pharmacokinetic study in renal transplanted patients receiving belatacept infusions. Belatacept serum concentrations were determined at several time points between belatacept infusions. A simple population pharmacokinetic model was developed to visualize measured and predicted belatacept serum concentrations. RESULTS: The assay range was 0.9-30 mg/L with accuracy within 91%-99% and coefficients of variation ranging from 1.2% to 3.6%. Predilution extended the measurement range to 130 mg/L with an accuracy of 90% and coefficients of variation of 3.8%. Samples were stable during storage at 4 degrees C for 15 days and during 2 freeze-thaw cycles. Belatacept concentrations were determined in a total of 203 serum samples collected during 26 infusion intervals from 5 renal transplant recipients. The population pharmacokinetic model visualized both measured and predicted concentrations. CONCLUSIONS: We have developed an automated, accurate, and precise assay for the determination of belatacept serum concentrations. The assay was successfully applied in a pharmacokinetic study in renal transplant recipients receiving belatacept infusions.*

30634590\_PD.txt

Title: Daily Nutritional Supplementation with Vitamin D(3) and Phenylbutyrate to Treatment-Naive HIV Patients Tested in a Randomized Placebo-Controlled Trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2019/01/04 00:00 [accepted]

Poor nutritional status is common among human immunodeficiency virus (HIV)-infected patients including vitamin D (vitD(3)) deficiency. We conducted a double-blinded, randomized, and placebo-controlled trial in Addis Ababa, Ethiopia, to investigate if daily nutritional supplementation with vitD(3) (5000 IU) and phenylbutyrate (PBA, 2 x 500 mg) could mediate beneficial effects in treatment-naive HIV patients. Primary endpoint: the change in plasma <P 0> HIV-1 </> comparing week 0 to 16 using modified intention-to-treat (mITT, n = 197) and per-protocol (n = 173) analyses. Secondary endpoints: longitudinal <P 0> HIV viral load </>, <P 0> T cell counts </>, <P 0> body mass index (BMI) </>, <P 0> middle-upper-arm circumference (MUAC) </>, and <P 0> 25(OH)D(3) </> levels in plasma. Baseline characteristics were detectable viral loads (median 7897 copies/mL), low CD4(+) (median 410 cells/microL), and elevated CD8(+) (median 930 cells/microL) T cell counts. Most subjects were vitD(3) deficient at enrolment, but a gradual and significant improvement of <P 0> vitD(3) </> status was demonstrated in the vitD(3) + PBA group compared with placebo (p < 0.0001) from week 0 to 16 (median 37.5 versus 115.5 nmol/L). No significant changes in <P 0> HIV viral load </>, <P 0>(E3) CD4(+) or <P 0> CD8(+) T cell counts </>, <P 0> body mass index (BMI) </> or <P 0> middle-upper-arm circumference (MUAC) </> could be detected. Clinical <P 38> adverse events </> were similar in both groups. Daily vitD(3) + PBA for 16 weeks was well-tolerated and effectively improved <P 0> vitD(3) </> status but did not reduce <P 0> viral load </>, restore <P 0> peripheral T cell counts </> or improve <P 0> body mass index (BMI) </> or <P 0> middle-upper-arm circumference (MUAC) </> in HIV patients with slow progressive disease. Clinicaltrials.gov NCT01702974.

30634657\_PD.txt

Title: The Effect of a Multidisciplinary Lifestyle Intervention on <P 0> Obesity </> Status, <P 0> Body Composition </>, <P 0> Physical Fitness </>, and <P 0> Cardiometabolic </> Risk Markers in Children and Adolescents with Obesity.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2019/01/05 00:00 [accepted]

This study aimed to develop a multidisciplinary lifestyle intervention program targeted at children and adolescents with moderate to severe obesity, and assess the additional effects of exercise intervention when compared to usual care. Overall, the 103 enrolled participants were >/=85th percentile of age and sex-specific body mass index (BMI). Participants were divided into groups that received 16 weeks of either usual care or exercise intervention. The <P 0> BMI </> z-score of the overall completers decreased by about 0.05 after the 16-week intervention (p = 0.02). After the intervention, only the exercise group had a significantly lower <P 0> BMI </> z-score than the baseline score by about 0.1 (p = 0.03), but no significant group by time interaction effects were observed. At the 16-week follow-up, significant group by time interaction effects were observed in percentage <P 0> body fat </> (%BF) (beta = -1.52, 95%CI = -2.58(-)-0.45), <P 0> lean body mass (LM) </> (beta = 1.20, 95%CI = 0.12(-)2.29), <P 0> diastolic blood pressure </> (beta = -5.24, 95%CI = -9.66(-)-0.83), <P 0> high-sensitivity C-reactive protein </> (beta = -1.67, 95%CI = -2.77(-)-1.01), and [T wall sit test] score (beta = 50.74, 95%CI = 32.30(-)69.18). We developed a moderate-intensity intervention program that can be sustained in the real-world setting and is practically applicable to both moderate and severe obesity. After interventions, the exercise group had lower percentage <P 0> body fat </> (%BF) and <P 0> cardiometabolic </> risk markers, and higher <P 0> lean body mass (LM) </> and <P 25> leg muscle strength </> compared to the usual care group.

30634687\_PD.txt

Title: Effects of Grape Pomace Polyphenolic Extract (Taurisolo((R))) in Reducing <P 0> Trimethylamine N-oxide (TMAO) </> Serum Levels in Humans: Preliminary Results from a Randomized, Placebo-Controlled, Cross-Over Study.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2019/01/07 00:00 [accepted]

Trimethylamine N-oxide (TMAO) is considered a novel risk factor for cardiovascular diseases. Several studies demonstrated that polyphenols are able to inhibit the growth of TMA-producing bacterial strains, and resveratrol (RSV) reduced TMAO levels in mice. In the present study, we evaluated the <P 0> Trimethylamine N-oxide (TMAO) </> -reducing effect of a novel nutraceutical formulation containing grape pomace extract in humans (Taurisolo((R))). The Taurisolo((R)) polyphenol content was evaluated by a High Performance Liquid Chromatography-diode-array detector (HPLC-DAD) method, and RSV was monitored as an indicative marker. After in vitro GI digestion, intestinal bioaccessibility of RSV was 92.3%. A randomized, placebo-controlled, cross-over trial was carried out to evaluate the <P 0> Trimethylamine N-oxide (TMAO) </> -reducing effect of Taurisolo((R)). In acute, the maximum levels of <P 0> resveratrol (RSV) </> were detected both in serum and whole blood 60 min after the administration of Taurisolo((R)); in chronic, a significant increase of <P 0> resveratrol (RSV) </> was detected in serum after the 4-week treatment. After 4 weeks, the levels of <P 0> Trimethylamine N-oxide (TMAO) </> were significantly decreased in the treatment group compared to placebo (63.6% vs. 0.54%, respectively, P < 0.0001). In conclusion, our data show that Taurisolo((R)) may represent a novel and useful natural remedy to reduce prognostic markers for incident cardiovascular events. Undoubtedly, further in vitro and in vivo studies need to be performed in order to elucidate possible mechanisms of action and corroborate our preliminary results.

30635141\_PD.txt

Title: Enteral lactoferrin supplementation for very preterm infants: a randomised placebo-controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Lancet (London, England)

Journal ID: 2985213R

Publication date: 2018/09/05 00:00 [accepted]

BACKGROUND: Infections acquired in hospital are an important cause of morbidity and mortality in very preterm infants. Several small trials have suggested that supplementing the enteral diet of very preterm infants with lactoferrin, an antimicrobial protein processed from cow's milk, prevents infections and associated complications. The aim of this large randomised controlled trial was to collect data to enhance the validity and applicability of the evidence from previous trials to inform practice. METHODS: In this randomised placebo-controlled trial, we recruited very preterm infants born before 32 weeks' gestation in 37 UK hospitals and younger than 72 h at randomisation. Exclusion criteria were presence of a severe congenital anomaly, anticipated enteral fasting for longer than 14 days, or no realistic prospect of survival. Eligible infants were randomly assigned (1:1) to receive either enteral bovine lactoferrin (150 mg/kg per day; maximum 300 mg/day; lactoferrin group) or sucrose (same dose; control group) once daily until 34 weeks' postmenstrual age. Web-based randomisation minimised for recruitment site, gestation (completed weeks), sex, and single versus multifetal pregnancy. Parents, caregivers, and outcome assessors were unaware of group assignment. The primary outcome was microbiologically confirmed or clinically suspected late-onset <P 0> infection </> (occurring >72 h after birth), which was assessed in all participants for whom primary outcome data was available by calculating the relative risk ratio with 95% CI between the two groups. The trial is registered with the International Standard Randomised Controlled Trial Number 88261002. FINDINGS: We recruited 2203 participants between May 7, 2014, and Sept 28, 2017, of whom 1099 were assigned to the lactoferrin group and 1104 to the control group. Four infants had consent withdrawn or unconfirmed, leaving 1098 infants in the lactoferrin group and 1101 in the sucrose group. Primary outcome data for 2182 infants (1093 [99.5%] of 1098 in the lactoferrin group and 1089 [99.0] of 1101 in the control group) were available for inclusion in the modified intention-to-treat analyses. 316 (29%) of 1093 infants in the intervention group acquired a late-onset <P 0> infection </> versus 334 (31%) of 1089 in the control group. The risk ratio adjusted for minimisation factors was 0.95 (95% CI 0.86-1.04; p=0.233). During the trial there were 16 <P 38> serious adverse events </> for infants in the lactoferrin group and 10 for infants in the control group. Two events in the lactoferrin group (one case of <P 0> blood in stool </> and one <P 1> death </> after intestinal perforation) were assessed as being possibly related to the trial intervention. INTERPRETATION: Enteral supplementation with bovine lactoferrin does not reduce the risk of late-onset <P 0> infection </> in very preterm infants. These data do not support its routine use to prevent late-onset infection and associated morbidity or mortality in very preterm infants. FUNDING: UK National Institute for Health Research Health Technology Assessment programme (10/57/49).

30636761\_PD.txt

Title: Clinical Outcome following Intra-articular Triamcinolone Injection in Osteoarthritic Knee at the Community: A Randomized Double Blind Placebo Controlled Trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Kathmandu University medical journal (KUMJ)

Journal ID: 101215359

Publication date: 2019/03/07 06:00 [medline]

Background Knee pain is one of the common complaints patients present with in any community based health camps and Osteoarthritis of knee is a usual diagnosis. Injecting a long acting steroid is a common practice to alleviate the symptoms of osteoarthritic knee. Objective To evaluate the clinical outcome of injecting Triamcinolone acetenoid in osteoarthritis of knee in a community set up over a randomized double-blind placebo control trial. Method A prospective, randomized, double blind, placebo control trial was carried out in community after obtaining the ethical clearance from the IRC. Patients with clinically diagnosed osteoarthritis of knee were injected either Triamcinolone or Placebo after recording the baseline scores of the knee by Knee injury and Osteoarthritis Outcome Score (KOOS) - Physical Function Short form (KOOS-PS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Visual Analogue Scale (VAS). The same tools were used at two, six and at twelve weeks post injection to evaluate the <P 25> functional </> outcome and <P 0> pain </>. Result One hundred and seventeen patients were available for analysis among which, 55(48.7%) patients received Triamcinolone and 58(51.3%) received placebo. The baseline status of knees of two groups was comparable at the start of study. There was significant <P 0> pain relief </> in the group receiving Triamcinolone at two and six week but not in twelve weeks. Group receiving placebo had <P 0> pain relief </> only for first two weeks. <P 25> Functional </> outcome was significantly improved compared to baseline in both the groups until six weeks however, in the triamcinolone group, it was significant until twelve weeks. No major <P 38> complications </> were noted. Conclusion Intra-articular injection of Triamcinolone acetenoid is effective in <P 0> symptoms control </> and improving <P 25> functional </> outcome in clinically diagnosed osteoarthritis of knees in community set up during health camps.

30642311\_PD.txt

Title: Mothers In Motion intervention effect on <P 26, 28> psychosocial health </> in young, low-income women with overweight or obesity.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC public health

Journal ID: 100968562

Publication date: 2019/01/16 06:00 [entrez]

BACKGROUND: Mothers in Motion (MIM), a community-based intervention program, was designed to help young, low-income women with overweight or obesity prevent further weight gain by promoting stress management, healthy eating, and physical activity. This paper presents the MIM's intervention effect on <P 28> self-efficacy </> to cope with stress, emotional <P 28> coping </> response, <P 33> social support </> for stress management, <P 28> stress </>, <P 0, 28> depressive symptoms </>, and <P 28>(E1) positive and <P 28> negative affect </>. METHODS: Participants (N = 612) were recruited from the Special Supplemental Nutrition Program for Women, Infants, and Children in Michigan. They were randomly assigned to an intervention group (410 participants) or comparison group (202 participants). During the 16-week intervention, intervention participants watched ten video lessons at home and joined ten peer support group teleconferences. Surveys with established validity and reliability were used to measure <P 28> self-efficacy </> to cope with stress, emotional <P 28> coping </> response, and <P 33> social support </> for stress management. The [T Perceived <P 28> Stress </> Scale], [T Center for Epidemiologic Studies <P 0, 28> Depression </> Scale], and [T <P 28>(E1) Positive and <P 28> Negative Affect </> Scale] were used to measure <P 28> stress </>, <P 0, 28> depressive symptoms </>, and <P 28>(E1) positive and <P 28> negative affect </>, respectively. A general linear mixed model was applied to test the intervention effect at the end of the 16-week intervention (T2, n = 338) and at three-month follow-up (T3, n = 311). RESULTS: At T2, the intervention group reported significantly higher <P 28> self-efficacy </> to cope with stress (effect size [Cohen's d] = 0.53), better emotional <P 28> coping </> response (d = 0.38), less <P 28> stress </> (d = 0.34), fewer <P 0, 28> depressive symptoms </> (d = - 0.27), and more <P 28> positive affect </> (d = 0.31) than the comparison group. However, there were no significant differences in <P 33> social support </> for stress management and <P 28> negative affect </> between these two groups. At T3, the intervention group still reported significantly higher <P 28> self-efficacy </> to cope with stress (d = 0.32) and better emotional <P 28> coping </> response (d = 0.34) than the comparison group but did not report significantly higher <P 33> social support </> for stress management, <P 28> stress </>, <P 0, 28> depressive symptoms </>, and <P 28>(E1) positive and <P 28> negative affect </>. CONCLUSIONS: To help young, low-income women with overweight or obesity manage stress, researchers and program planners may consider focusing on building <P 28> self-efficacy </> to cope with stress. TRIAL REGISTRATION: Clinical Trials NCT01839708 ; registered February 28, 2013.

30643052\_PD.txt

Title: [Evaluation of intervention program for risk behaviors of unintentional injury among school age children].

Publication Type: Randomized Controlled Trial

Journal-Name:Zhong nan da xue xue bao. Yi xue ban = Journal of Central South University. Medical sciences

Journal ID: 101230586

Publication date: 2019/02/12 06:00 [medline]

OBJECTIVE: To develop an intervention protocol for children's unintentional injury risk behaviors, and to evaluate the <P 32> feasibility </> of the protocol. Methods: By theoretically analyzing the influential factors for children's unintentional injury risk behaviors, children's cognitive development characteristics and the social learning theory, an intervention protocol was established on the basis of changing the unintentional injury attribution and negative information transmission of risk behavior consequences. A primary school in Changsha city was selected by random cluster sampling. A community-based randomized controlled trial was conducted on the selected students once a week for 5 consecutive weeks. The scores of unintentional injury <P 25> risk behavior </> before intervention, 3 months and 6 months after intervention, and the frequency before intervention and 6 months after intervention, were collected and compared. Results: A total of 194 children were included in the study: 98 in the intervention group; 96 in the control group; 96 (49.5%) boys and 98 (50.5%) girls between 7 and 8 years old. The scores of unintentional injury <P 25> risk behavior </> for children in the intervention group at 3 and 6 months after intervention were 14.42+/-5.67 and 14.14+/-8.95, respectively, lower than those before the intervention (16.85+/-8.48) and in the control group (P=0.001). The number of minor unintentional <P 0> injuries </> in the intervention group decreased from 119 to 56, and the number of children suffering 2 or more injuries dropped from 34 to 10 (P<0.001) at 6 months after the intervention, while both of them were lower than that in the control group (P=0.011). Similar changes were observed in some slight or more serious unintentional <P 0> injuries </> (P=0.030). Conclusion: The protocol for changing the attribution to unintentional injury and negative information transmission for risk behavior consequences was proved to effectively reduce children's unintentional injury <P 25> risk behaviors </> and relevant events.

30643068\_PD.txt

Title: [Efficacy of fluvoxamine combined with extended-release methylphenidate on treatment-refractory obsessive-compulsive disorder].

Publication Type: Journal Article

Journal-Name:Zhong nan da xue xue bao. Yi xue ban = Journal of Central South University. Medical sciences

Journal ID: 101230586

Publication date: 2019/02/14 06:00 [medline]

OBJECTIVE: To observe the clinical efficacy of dopamine modulator methylphenidate (MPH) of extended-release formulations (MPH-ER) augmentation of ongoing fluvoxamine treatment in refractory obsessive-compulsive disorder (OCD) and its effects on patient's <P 0, 28> anxiety </> and <P 0> sleep quality </>. Methods: A pilot randomized, placebo-controlled, and double-blind trial was conducted at an outpatient, single-center academic setting. Participants included 44 adults with serotonin reuptake inhibitor treatment-refractory OCD and they received a stable fluvoxamine pharmacotherapy with [T Yale-Brown <P 0, 28> Obsessive Compulsive </> Scale (Y-BOCS)] scores higher than 20. The 44 patients were randomly assigned into a study group and a control group, with 22 patiencs in each group. Fluvoxamine and MPH-ER were given to the study group, while fluvoxamine and placebo were given to the control group, with 8 weeks of the treatment course. [T Yale-Brown <P 0, 28> Obsessive Compulsive </> Scale (Y-BOCS)], [T Hamilton <P 0, 28> Anxiety </> Scale (HAMA)] were used to assess the efficacy, [T Pittsburgh <P 0> Sleep Quality </> Index (PSQI)] was used to evaluate the <P 0> sleep quality </>, and [T Treatment Emergent Symptom Scale (TESS)] was used to evaluate the <P 38> side effects </>. Data were analyzed in the intention-to-treat sample. Results: The improvement in the [T Yale-Brown <P 0, 28> Obsessive Compulsive </> Scale (Y-BOCS)] total score, [T Yale-Brown <P 0, 28> Obsessive Compulsive </> Scale (Y-BOCS)] <P 0, 28> obsession </> subscale score and [T Hamilton <P 0, 28> Anxiety </> Scale (HAMA)] score were more prominent in the study group than those in the control group (P<0.001). There was no significant difference in [T Pittsburgh <P 0> Sleep Quality </> Index (PSQI)] score and [T Treatment Emergent Symptom Scale (TESS)] score between the two groups. MPH-ER was well <P 32> tolerated </>. Conclusion: Fluvoxamine combined with MPH-ER is effective in the treatment of refractory obsessive-compulsive disorder. It can improve <P 0, 28> anxiety </> and has no <P 38> adverse effect </> on <P 0> sleep quality </>.