30572545\_PD.txt

Title: Comparing the effect between continuous infusion and intermittent bolus of rocuronium for intraoperative neurophysiologic monitoring of neurointervention under general anesthesia.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/08 06:00 [medline]

BACKGROUND: Medical researchers have been reluctant to use neuromuscular blocking drugs (NMBD) during the use of intraoperative motor evoked potential (MEP) monitoring despite the possibility of patient movement. In this study, we compared the effects of no NMBD and continuous rocuronium infusion on the incidence of patient <P 0> involuntary movement </> and <P 0> motor evoked potential (MEP) </> monitoring. METHODS: In this study, 80 patients who underwent neuro intervention with MEP monitoring were randomly assigned into 2 groups. After an anesthetic induction, bolus of rocuronium 0.1 mg/kg was injected when it was needed (for patient <P 0> involuntary movement </> or at the request of the surgeon) in group B, and 5 mcg/kg/min of rocuronium were infused in group I study participants. The incidence of patient <P 0> involuntary movement </> and <P 0> spontaneous respiration </>, the mean <P 0> MEP amplitude </>, coefficient of variation (CV), the incidence of <P 0> MEP stimulus change </> and <P 0> train-of-four (TOF) count </> were compared. RESULTS: The incidence of <P 0> involuntary movement </> and <P 0> spontaneous movement </> were measured as significantly lower in group I (P < .05). The incidence of undetectable <P 0> MEP </> did not differ as measured in both groups. The means and CVs of <P 0> MEP amplitude </> in all limbs were significantly lower in group I. The mean <P 0> train-of-four (TOF) counts </> from 30 to 80 min of operation were significantly higher in group B. CONCLUSION: We conclude that the continuous infusion of rocuronium effectively inhibited the <P 0> involuntary movement </> and <P 0> spontaneous respiration </> of the patient while enabling MEP monitoring.

30572548\_PD.txt

Title: Rehabilitation treatment of spastic cerebral palsy with radial extracorporeal shock wave therapy and rehabilitation therapy.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/08 06:00 [medline]

This aims to investigate the effect of combined use of radial extracorporeal shock wave therapy (rESWT) and conventional rehabilitation therapy on postoperative rehabilitation of children with spastic cerebral palsy. Children with spastic cerebral palsy 6 weeks after multistage surgery were randomly divided into treatment group (received rESWT and conventional rehabilitation therapy) and control group (received conventional rehabilitation only). Before treatment, 2 weeks and 1 month after treatment, the [T <P 25> Gross Motor Function {Measure (GMFM)], [T modified Ashworth Scale (MAS)]} of the hamstrings and triceps </>, <P 0> plantar area </> and <P 0> plantar pressure </> were examined for efficacy assessment. A total of 82 children with spastic cerebral palsy were recruited, including 43 children in treatment group and 39 children in control group. There was no significant difference in the age, MAS score, and GMFM score between the 2 groups before treatment. There were statistically significant differences between the 2 groups at 2 weeks and 4 weeks after treatment, including the [T modified Ashworth Scale (MAS)] score, [T <P 25> Gross Motor Function </> Measure (GMFM)] score, <P 0> plantar area </> and <P 0> plantar pressure </> (P < .05). Within groups, there were also significant differences at different times (P < .05).The rESWT combined with rehabilitation can quickly and effectively relieve <P 0, 25> paralysis </> of lower extremities, reduce the <P 0>(S2) tension of hamstrings <P 0> and calf muscles </>, relieve <P 0> muscle spasm </>, and rapidly improve <P 25> limb function </> in children with spastic cerebral palsy.

30572864\_PD.txt

Title: The impact of unhealthy food sponsorship vs. pro-health sponsorship models on young adults' <P 29> food preferences </>: a randomised controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC public health

Journal ID: 100968562

Publication date: 2018/12/22 06:00 [entrez]

BACKGROUND: Unhealthy foods are promoted heavily, through food company sponsorship of elite sport, resulting in extensive exposure among young adults who are avid sport spectators. This study explores the effects of sponsorship of an elite sporting event by: (A) non-food brands (control), (B) unhealthy food brands, (C) healthier food brands, or (D) an obesity prevention public health campaign on young adults' <P 29> brand awareness </>, <P 29> attitudes </>, <P 29> image perceptions </>, <P 29> event-sponsor fit perceptions </>, and <P 29> preference </> for food sponsors' products. METHODS: A between-subjects web-based experiment was conducted, consisting of four sponsorship conditions (A through D) featuring three product categories within each condition. Australian adults (N = 1132) aged 18-24 years were recruited via a national online panel. Participants viewed promotional videos and news stories about an upcoming international, multi-sport event (with sponsor content edited to reflect each condition), completed a distractor task, and then answered questions assessing the response variables. Regression analyses were conducted to test for differences by sponsorship condition on the respective outcome measures. RESULTS: Compared to the control condition, unhealthy food sponsorship promoted higher <P 29> awareness </> of, and more favourable <P 29> attitudes </> towards, unhealthy food sponsor brands. Unhealthy food sponsorship also led to greater perceived <P 29>(E1) event-sponsor fit and <P 29> transfer of perceptions </> of the sporting event to the unhealthy food sponsor brands, relative to the control group. Exposure to sponsorship for healthier foods produced similar sponsorship effects for healthier food sponsor brands, as well as prompting a significant increase in the proportion of young adults showing a <P 29> preference </> for these products. Obesity prevention campaign sponsorship promoted higher campaign <P 29> awareness </> and <P 29> perceived event-sponsor fit </>, but did not impact food <P 29> attitudes </> or <P 29> preference </> for unhealthy versus healthier foods. CONCLUSION: Findings suggest that restricting elite sport sponsorship to healthier food brands that meet set nutritional criteria could help promote healthier eating among young adults. Sporting organisations should be encouraged to seek sponsorship from companies who produce healthier food brands and government-funded social marketing campaigns. CLINICAL TRIAL REGISTRATION: Australian New Zealand Clinical Trials Registry (ANZCTR) registration number ACTRN12618000368235 . Retrospectively registered 12 March 2018.

30572894\_PD.txt

Title: Prospective, randomized, double-blinded, placebo-controlled study on safety and <P 32> tolerability </> of the krill powder product in overweight subjects with moderately elevated blood pressure.

Publication Type: Randomized Controlled Trial

Journal-Name:Lipids in health and disease

Journal ID: 101147696

Publication date: 2018/12/22 06:00 [entrez]

BACKGROUND: Krill powder is rich in bioactive ingredients such as eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), phospholipids, protein and astaxanthin. Containing dominantly EPA, it is considered to be effective in lowering lipids, foremost serum triglycerides and LDL cholesterol. Krill-derived protein hydrolysates/peptides may have positive effect on blood pressure and astaxanthin has anti-oxidative and anti-inflammatory properties. Thus, krill powder has a lot of potential in improving lipid and metabolic profile and reinforcing the activity of the antioxidant system. However, randomized clinical trials on krill powder are scarce and systematic data of krill meal on human safety is limited. Some of the earlier studies have reported several, non-serious adverse events, mostly related to gastrointestinal tract, but systematic sufficiently powered study on safety is lacking. The aim of this study was to collect data on safety and <P 32> tolerability </> of krill powder in humans and simultaneously gain efficacy data by measuring the risk factors for cardiovascular disease. METHODS: The study was a randomised, double-blinded, placebo-controlled intervention study with 35 overweight subjects with mildly or moderately elevated blood pressure, who took 4 g krill oil powder or 4 g of placebo during an 8-week follow-up period. The study consisted of a pre-screening, screening, day 0 baseline (randomization visit) and three follow-up visits on days 14, 28 and 56. The reported <P 38> adverse events </> in the groups were compared as primary endpoint and <P 0> haematological </> safety parameters and changes in <P 0>(E1) systolic and <P 0> diastolic pressure </> and blood total and <P 0>(E1) lipoprotein <P 0> lipids </> were measured as secondary end points. RESULTS: There were in total 80 reported <P 38> adverse events </> during the follow-up; 50 in placebo and 30 in krill powder group. <P 0> Gastrointestinal symptoms </> (<P 0> flatulence </>, (<P 0> heartburn </> and <P 0> diarrhea </>) were the most commonly reported among those probably related to the test products. No <P 38> serious adverse events </> were reported. The mean value of all measured <P 0> hematology </> variables remained within the reference values in all study subject and no significant changes were observed in <P 0> blood pressure </> or <P 0> lipid </> values. CONCLUSIONS: The results seem to indicate that using krill powder as a source for EPA and DHA is safe in therapeutic dose and the risk of <P 38> adverse events </>, let alone serious ones, is low. TRIAL REGISTRATION: ClinicalTrials.gov, NCT03112083 , retrospectively registered.

30572916\_PD.txt

Title: A multi-center, randomized controlled clinical trial of the application of a shortened protocol of long-acting Triptorelin down-regulated prior to IVF/ICSI among patients with endometriosis: A protocol.

Publication Type: Multicenter Study

Journal-Name:Reproductive health

Journal ID: 101224380

Publication date: 2018/12/22 06:00 [entrez]

BACKGROUND: Endometriosis is the major cause of progressive pelvic pain and subfertility. Up to 50% of reproductive-age women suffer from pelvic pain. Endometriosis is a classic indication for IVF. Compared with women whose inability to procreate is caused by simple tubal infertility, women with endometriosis often have lower pregnancy rates following in vitro fertilization/intracytoplasmic sperm injection (IVF/ICSI). The administration of gonadotrophin-releasing hormone (GnRH) agonists prior to IVF/ICSI can improve the successful pregnancy rate. Whether a briefer treatment interval would be efficacious has not been studied. METHODS/DESIGN: Eligible and consenting women will be randomly assigned to one of two treatments (one cycle of a GnRH agonist or two cycles of a GnRH agonist) prior to IVF/ICSI using a table of random numbers. The primary outcome of this trial is <P 0> clinical pregnancy </> rate. Other outcomes include <P 0> gonadotrophin (Gn) duration </>, the total <P 32> dose of follicle-stimulating hormone (FSH) </> used, number of <P 0> oocytes retrieved </>, number of <P 0> embryos available for transfer </>, <P 0> implantation </> rate, the <P 0> abortion </> rate, <P 1> live birth </> rate, and incidence of moderate-to-severe <P 0> ovarian hyperstimulation </>. The sample size of this trial is estimated to be 421 participants for each of the two arms. Appropriate interim analyses will be conducted by a data monitoring and ethics committee (DMEC), and the final test will be an intention-to-treat analysis. TRIAL REGISTRATION: This trial has been assigned the following registry number: NCT03006406 .

*30572941\_PD.txt*

*Title: "We find what we look for, and we look for what we know": factors interacting with a mental health training program to influence its expected outcomes in Tunisia.*

*Publication Type: Randomized Controlled Trial*

*Journal-Name:BMC public health*

*Journal ID: 100968562*

*Publication date: 2018/12/22 06:00 [entrez]*

*BACKGROUND: Primary care physicians (PCPs) working in mental health care in Tunisia often lack knowledge and skills needed to adequately address mental health-related issues. To address these lacunas, a training based on the Mental Health Gap Action Programme (mhGAP) Intervention Guide (IG) was offered to PCPs working in the Greater Tunis area between February and April 2016. While the mhGAP-IG has been used extensively in low- and middle-income countries (LMICs) to help build non-specialists' mental health capacity, little research has focused on how contextual factors interact with the implemented training program to influence its expected outcomes. This paper's objective is to fill that lack. METHODS: We conducted a case study with a purposeful sample of 18 trained PCPs. Data was collected by semi-structured interviews between March and April 2016. Qualitative data was analyzed using thematic analysis. RESULTS: Participants identified more barriers than facilitators when describing contextual factors influencing the mhGAP-based training's expected outcomes. Barriers were regrouped into five categories: structural factors (e.g., policies, social context, local workforce development, and physical aspects of the environment), organizational factors (e.g., logistical issues for the provision of care and collaboration within and across healthcare organizations), provider factors (e.g., previous mental health experience and personal characteristics), patient factors (e.g., beliefs about the health system and healthcare professionals, and motivation to seek care), and innovation factors (e.g., training characteristics). These contextual factors interacted with the implemented training to influence knowledge about pharmacological treatments and symptoms of mental illness, confidence in providing treatment, negative beliefs about certain mental health conditions, and the understanding of the role of PCPs in mental health care delivery. In addition, post-training, participants still felt uncomfortable with certain aspects of treatment and the management of some mental health conditions. CONCLUSIONS: Findings highlight the complexity of implementing a mhGAP-based training given its interaction with contextual factors to influence the attainment of expected outcomes. Results may be used to tailor structural, organizational, provider, patient, and innovation factors prior to future implementations of the mhGAP-based training in Tunisia. Findings may also be used by decision-makers interested in implementing the mhGAP-IG training in other LMICs.*

30575473\_PD.txt

Title: Radical Prostatectomy or Watchful Waiting in Prostate Cancer - 29-Year Follow-up.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/15 06:00 [medline]

BACKGROUND: Radical prostatectomy reduces mortality among men with clinically detected localized prostate cancer, but evidence from randomized trials with long-term follow-up is sparse. METHODS: We randomly assigned 695 men with localized prostate cancer to watchful waiting or radical prostatectomy from October 1989 through February 1999 and collected follow-up data through 2017. Cumulative incidence and relative risks with 95% confidence intervals for <P 1> death from any cause </>, <P 1> death from prostate cancer </>, and <P 0> metastasis </> were estimated in intention-to-treat and per-protocol analyses, and numbers of years of life gained were estimated. We evaluated the prognostic value of histopathological measures with a Cox proportional-hazards model. RESULTS: By December 31, 2017, a total of 261 of the 347 men in the radical-prostatectomy group and 292 of the 348 men in the watchful-waiting group had <P 1> died </>; 71 <P 1> deaths {in the radical-prostatectomy group and 110 in the watchful-waiting group were} due to prostate cancer </> (relative risk, 0.55; 95% confidence interval [CI], 0.41 to 0.74; P<0.001; absolute difference in risk, 11.7 percentage points; 95% CI, 5.2 to 18.2). The number needed to treat to avert one <P 1> death from any cause </> was 8.4. At 23 years, a mean of 2.9 extra years of life were gained with radical prostatectomy. Among the men who underwent radical prostatectomy, extracapsular extension was associated with a risk of <P 1> death from prostate cancer </> that was 5 times as high as that among men without extracapsular extension, and a Gleason score higher than 7 was associated with a risk that was 10 times as high as that with a score of 6 or lower (scores range from 2 to 10, with higher scores indicating more aggressive cancer). CONCLUSIONS: Men with clinically detected, localized prostate cancer and a long life expectancy benefited from radical prostatectomy, with a mean of 2.9 years of life gained. A high Gleason score and the presence of extracapsular extension in the radical prostatectomy specimens were highly predictive of <P 1> death from prostate cancer </>. (Funded by the Swedish Cancer Society and others.).

30575484\_PD.txt

Title: Sorafenib for Advanced and Refractory Desmoid Tumors.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/12 06:00 [medline]

BACKGROUND: Desmoid tumors (also referred to as aggressive fibromatosis) are connective tissue neoplasms that can arise in any anatomical location and infiltrate the mesentery, neurovascular structures, and visceral organs. There is no standard of care. METHODS: In this double-blind, phase 3 trial, we randomly assigned 87 patients with progressive, symptomatic, or recurrent desmoid tumors to receive either sorafenib (400-mg tablet once daily) or matching placebo. Crossover to the sorafenib group was permitted for patients in the placebo group who had disease progression. The primary end point was investigator-assessed <P 0, 1> progression-free survival </>; rates of <P 0> objective response </> and <P 38> adverse events </> were also evaluated. RESULTS: With a median follow-up of 27.2 months, the 2-year <P 0, 1> progression-free survival </> rate was 81% (95% confidence interval [CI], 69 to 96) in the sorafenib group and 36% (95% CI, 22 to 57) in the placebo group (hazard ratio for <P 0> progression </> or <P 1> death </>, 0.13; 95% CI, 0.05 to 0.31; P<0.001). Before crossover, the objective <P 0> response </> rate was 33% (95% CI, 20 to 48) in the sorafenib group and 20% (95% CI, 8 to 38) in the placebo group. The median <P 0> time to an objective response </> among patients who had a response was 9.6 months (interquartile range, 6.6 to 16.7) in the sorafenib group and 13.3 months (interquartile range, 11.2 to 31.1) in the placebo group. The objective <P 0> responses </> are ongoing. Among patients who received sorafenib, the most frequently reported <P 38> adverse events </> were grade 1 or 2 events of <P 0> rash </> (73%), <P 0> fatigue </> (67%), <P 0> hypertension </> (55%), and <P 0> diarrhea </> (51%). CONCLUSIONS: Among patients with progressive, refractory, or symptomatic desmoid tumors, sorafenib significantly prolonged <P 0, 1> progression-free survival </> and induced durable responses. (Funded by the National Cancer Institute and others; ClinicalTrials.gov number, NCT02066181 .).

30575489\_PD.txt

Title: Fracture Prevention with Zoledronate in Older Women with Osteopenia.

Publication Type: Multicenter Study

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/12 06:00 [medline]

BACKGROUND: Bisphosphonates prevent fractures in patients with osteoporosis, but their efficacy in women with osteopenia is unknown. Most fractures in postmenopausal women occur in those with osteopenia, so therapies that are effective in women with osteopenia are needed. METHODS: We conducted a 6-year, double-blind trial involving 2000 women with osteopenia (defined by a T score of -1.0 to -2.5 at either the total hip or the femoral neck on either side) who were 65 years of age or older. Participants were randomly assigned to receive four infusions of either zoledronate at a dose of 5 mg (zoledronate group) or normal saline (placebo group) at 18-month intervals. A dietary calcium intake of 1 g per day was advised, but calcium supplements were not provided. Participants who were not already taking vitamin D supplements received cholecalciferol before the trial began (a single dose of 2.5 mg) and during the trial (1.25 mg per month). The primary end point was the <P 0> time to first occurrence of a nonvertebral or vertebral fragility fracture </>. RESULTS: At baseline, the mean (+/-SD) age was 71+/-5 years, the T score at the femoral neck was -1.6+/-0.5, and the median 10-year risk of hip fracture was 2.3%. A <P 0> fragility fracture </> occurred in 190 women in the placebo group and in 122 women in the zoledronate group (hazard ratio with zoledronate, 0.63; 95% confidence interval, 0.50 to 0.79; P<0.001). The number of women that would need to be treated to prevent the occurrence of a fracture in 1 woman was 15. As compared with the placebo group, women who received zoledronate had a lower risk of <P 0> nonvertebral fragility fractures </> (hazard ratio, 0.66; P=0.001), <P 0> symptomatic fractures </> (hazard ratio, 0.73; P=0.003), <P 0> vertebral fractures </> (odds ratio, 0.45; P=0.002), and <P 0> height loss </> (P<0.001). CONCLUSIONS: The risk of <P 0>(E2) nonvertebral or <P 0> vertebral fragility fractures </> was significantly lower in women with osteopenia who received zoledronate than in women who received placebo. (Funded by the Health Research Council of New Zealand; Australian New Zealand Clinical Trials Registry number, ACTRN12609000593235 .).

30575490\_PD.txt

Title: FOLFIRINOX or Gemcitabine as Adjuvant Therapy for Pancreatic Cancer.

Publication Type: Comparative Study

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/12 06:00 [medline]

BACKGROUND: Among patients with metastatic pancreatic cancer, combination chemotherapy with fluorouracil, leucovorin, irinotecan, and oxaliplatin (FOLFIRINOX) leads to longer overall survival than gemcitabine therapy. We compared the efficacy and safety of a modified FOLFIRINOX regimen with gemcitabine as adjuvant therapy in patients with resected pancreatic cancer. METHODS: We randomly assigned 493 patients with resected pancreatic ductal adenocarcinoma to receive a modified FOLFIRINOX regimen (oxaliplatin [85 mg per square meter of body-surface area], irinotecan [180 mg per square meter, reduced to 150 mg per square meter after a protocol-specified safety analysis], leucovorin [400 mg per square meter], and fluorouracil [2400 mg per square meter] every 2 weeks) or gemcitabine (1000 mg per square meter on days 1, 8, and 15 every 4 weeks) for 24 weeks. The primary end point was <P 0, 1> disease-free survival </>. Secondary end points included <P 1> overall survival </> and safety. RESULTS: At a median follow-up of 33.6 months, the median <P 0, 1> disease-free survival </> was 21.6 months in the modified-FOLFIRINOX group and 12.8 months in the gemcitabine group (stratified hazard ratio for <P 0> cancer-related event </>, <P 0> second cancer </>, or <P 1> death </>, 0.58; 95% confidence interval [CI], 0.46 to 0.73; P<0.001). The <P 0, 1> disease-free survival </> rate at 3 years was 39.7% in the modified-FOLFIRINOX group and 21.4% in the gemcitabine group. The median <P 1> overall survival </> was 54.4 months in the modified-FOLFIRINOX group and 35.0 months in the gemcitabine group (stratified hazard ratio for <P 1> death </>, 0.64; 95% CI, 0.48 to 0.86; P=0.003). The <P 1> overall survival </> rate at 3 years was 63.4% in the modified-FOLFIRINOX group and 48.6% in the gemcitabine group. <P 38> Adverse events </> of grade 3 or 4 occurred in 75.9% of the patients in the modified-FOLFIRINOX group and in 52.9% of those in the gemcitabine group. One patient in the gemcitabine group <P 1> died </> from <P 38> toxic </> effects (<P 0> interstitial pneumonitis </>). CONCLUSIONS: Adjuvant therapy with a modified FOLFIRINOX regimen led to significantly longer <P 1> survival </> than gemcitabine among patients with resected pancreatic cancer, at the expense of a higher incidence of <P 38> toxic </> effects. (Funded by R&D Unicancer and others; ClinicalTrials.gov number, NCT01526135 ; EudraCT number, 2011-002026-52 .).