30593158\_PD.txt

Title: Randomized study of the impact of a therapeutic education program on patients suffering from chronic low-back pain who are treated with transcutaneous electrical nerve stimulation.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/05 06:00 [medline]

BACKGROUND: Transcutaneous electrical nerve stimulation (TENS) is often used for the treatment of low-back pain (LBP). However, its effectiveness is controversial. OBJECTIVE: To determine the efficacy of TENS in the treatment LBP when associated to a therapeutic education program (TEP). DESIGN: Open randomized monocentric study. SETTING: University hospital between 2010 and 2014. PATIENTS: A total of 97 patients suffering from LBP. INTERVENTIONS: Routine care (TENS group) or routine care plus a therapeutic education program (TENS-TEP group) based on consultation support by a pain resource nurse. MAIN OUTCOME MEASURES: [T EIFEL] and [T Dallas <P 0> Pain </> Questionnaire] scores. RESULTS: Twenty-two patients (44%) were still assessable at the end-of-study visit, whereas 33 (70%) were assessable at the same time point in the TENS-TEP group (P = .013). The [T EIFEL] score and the [T Dallas <P 0> Pain </> Questionnaire] score had a similar evolution over time between groups (P = .18 and P = .50 respectively). Similarly, there were no significant differences between the groups with respect to <P 0> resting pain </> scores (P = .94 for back pain and P = .16 for leg pain) and <P 0> movement pain </> scores (P = .52 for back pain and P = .56 for leg pain). At Month 6, there was no significant difference between the groups (P = .85) with regard to <P 36> analgesics </> and <P 26> social </> impact. Two patients presented a <P 38> serious adverse event </> during the study (one in each group) but non-attributable to the treatment studied. CONCLUSION: This study does not support the use of TENS in the treatment of patients with chronic LBP even though patients benefited from a therapeutic education program by a pain resource nurse. However, the higher number of premature <P 32> withdrawals </> in the TENS group may be due to early <P 32> withdrawal </> of patients who did not experience improvement of their symptoms.

30593164\_PD.txt

Title: Lactulose for the treatment of Chinese children with chronic constipation: A randomized controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/05 06:00 [medline]

BACKGROUND: This study aimed to investigate the efficacy and safety of lactulose for the treatment of Chinese children with chronic constipation. METHODS: A total of 100 children with chronic constipation were included in this randomized controlled trial. They were equally and randomly allocated to a treatment group (n = 50) and a placebo group (n = 50). The participants in the treatment group received lactulose, while the subjects in the placebo group received placebo intervention. The children in both groups were treated for a total of 6 weeks. The primary outcome was daily <P 0> stool </> frequency. The secondary outcomes consisted of <P 0> stool consistency </>, measured by the Bristol Stool Form Scale, <P 0> abdominal pain </>, <P 0> flatulence </>, as well as the <P 38> adverse events </>. All outcomes were measured at baseline and after 6-weeks treatment. RESULTS: After 6 weeks treatment, lactulose showed better outcomes in daily <P 0> stool frequency </> (P < .01), and <P 0> stool consistency </> (P < .01), except the <P 0> abdominal pain </> (P = .24), and <P 0> flatulence </> (P = .44), compared with the placebo. Additionally, no significant differences regarding all <P 38> adverse events </> were detected between 2 groups. CONCLUSION: The results of this study found that lactulose is efficacious for Chinese children with chronic constipation after 6-weeks of treatment.

30593268\_PD.txt

Title: Effect of transcutaneous electrical acupoint stimulation on the effective <P 32> concentration </> (EC50) of remifentanil suppressing <P 0> responses </> to tracheal extubation in elderly patients.

Publication Type: Randomized Controlled Trial

Journal-Name:Medicine

Journal ID: 2985248R

Publication date: 2019/01/09 06:00 [medline]

Transcutaneous electrical acupoint stimulation (TEAS) is a emerging treatment which combines transcutaneous electrical nerve stimulation with traditional acupoint therapy. The present study was aimed to evaluate the effect of TEAS on the effective <P 32> concentration </> (EC50) of remifentanil suppressing tracheal extubation response in elderly patients.Fifty-three patients undergoing spine surgery were randomly divided into 2 groups: control group (group C, n = 26) and transcutaneous electrical acupoint stimulation group (group TEAS, n = 27). The effective <P 32> concentration </> values for remifentanil TCI were determined using sequential method and probit analysis.The remifentanil effective <P 32> concentration </> (EC50) of that suppressed responses to extubation during anesthetic emergence was 1.20 ng/mL in group TEAS, a value that was significantly lower than the 1.64 ng/mL needed by patients in group C.The TEAS can enhance the efficacy of remifentanil on suppressing <P 0> responses </> to tracheal extubation in elderly patients, the effective <P 32> concentration </> (EC50) of remifentanil can reduce approximately 27% compared with group C.

30593268\_PD.txt

Title: Does the "delayed start" protocol with gonadotropin-releasing hormone antagonist improve the <P 0> pregnancy </> outcome in Bologna poor responders? a randomized clinical trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Reproductive biology and endocrinology : RB&E

Journal ID: 101153627

Publication date: 2018/12/30 06:00 [entrez]

BACKGROUND: Recently, a novel approach with delaying the start of controlled ovarian stimulation along with gonadotropin-releasing hormone (GnRH) antagonist pretreatment for 7 days after estrogen priming for further suppression of endogenous follicle stimulating hormone (FSH) during the early follicular phase, resulting in more FSH-responsive follicles and thus improving synchronous follicular development was introduced. Two clinical trials have examined this strategy and reported controversial results. This study aimed to compare the effect of delayed-start GnRH antagonist protocol and standard GnRH antagonist in patients with poor ovarian response (POR) undergoing in vitro fertilization (IVF)/ intracytoplasmic sperm injection (ICSI). METHODS: This randomized clinical trial was conducted at infertility department of Royan Institute from January 2017 to June 2018. Poor ovarian response was defined according to the Bologna criteria. The eligible women were randomly allocated into an experimental and control groups. In experimental group, patients received delayed-start GnRH antagonist protocol with estrogen priming followed by early follicular-phase GnRH antagonist treatment for 7 days before ovarian stimulation with gonadotropin and in control group, patients treated with estrogen priming antagonist protocol. <P 0> In vitro fertilization (IVF) </> / <P 0> intracytoplasmic sperm injection (ICSI) </> outcomes were compared between groups. RESULTS: Among all the 250 patients examined 156 women were eligible for study and finally 120 patients were allocated to intervention (n = 60) and control (n = 60) groups. Demographic characteristics and hormonal profiles of the patients did not differ between groups. The statistical analysis showed that there were significant differences between groups regarding the total <P 32> dose </> of used gonadotropins (P < 0.001), <P 0> stimulation duration </> (P < 0.001), number of <P 0> retrieved oocytes </> (P = 0.01) and top quality <P 0> embryo </> (P < 0.001) and also <P 32> cancellation </> (P = 0.002) and <P 0> fertilization </> rates (P = 0.002). CONCLUSION: On the basis of present results the delayed-start protocol in poor responders can improve the <P 0> fertilization </> rate and <P 0>(E1) quality of <P 0> embryos </> and reduce the <P 32> cycle cancellation </> but have no significant effect on <P 0> clinical pregnancy </> rate; however, larger randomized clinical trials are required to compare it with other protocols. TRIAL REGISTRATION: NCT, NCT03134690. Registered 1 May 2017 - Retrospectively registered, http://www.clinicaltrial.gov / NCT03134690.

30594122\_PD.txt

Title: Preventive effects of galcanezumab in adult patients with episodic or chronic migraine are persistent: data from the phase 3, randomized, double-blind, placebo-controlled EVOLVE-1, EVOLVE-2, and REGAIN studies.

Publication Type: Journal Article

Journal-Name:The journal of headache and pain

Journal ID: 100940562

Publication date: 2018/12/31 06:00 [entrez]

BACKGROUND: Maintenance of effect following treatment with galcanezumab compared to placebo in adult patients with episodic or chronic migraine was evaluated. METHODS: In 2 similarly designed studies of patients with episodic migraine (6 months) and 1 study of patients with chronic migraine (3 months), patients randomized in a 1:1:2 ratio received a subcutaneous injection of galcanezumab 120 mg/month (after an initial loading dose of 240 mg) or 240 mg/month or placebo. Maintenance of effect during the double-blind phase was evaluated based on a comparison of the percentages of galcanezumab- and placebo-treated patients with maintenance of 30, 50, 75, and 100% <P 0> response </> (defined as >/=30, >/=50, >/=75, and 100% reduction from baseline in monthly migraine headache days [MHD]) at an individual patient level. Logistic regression analyses were used for between treatment comparisons. RESULTS: A total of 1773 adult patients with episodic migraine (n = 444 for galcanezumab 120 mg; n = 435 for galcanezumab 240 mg; n = 894 for placebo for 2 studies pooled) and 1113 patients with chronic migraine (n = 278 for galcanezumab 120 mg; n = 277 for galcanezumab 240 mg; n = 558 for placebo) were evaluated. In patients with episodic migraine, >/=50% response was maintained in 41.5 and 41.1% of galcanezumab-treated patients (120 mg and 240 mg, respectively) for >/=3 consecutive months (until patient's endpoint) and 19.0 and 20.5%, respectively, for 6 consecutive months and was significantly greater than the 21.4 and 8.0% of placebo-treated patients at >/=3 and 6 months consecutively (P < 0.001). Approximately 6% of galcanezumab-treated patients maintained >/=75% <P 0> response </> all 6 months versus 2% of placebo-treated patients. Few galcanezumab-treated patients maintained 100% <P 0> response </>. In patients with chronic migraine, 29% of galcanezumab-treated patients maintained >/=30% <P 0> response </> all 3 months compared to 16% of placebo patients while >/=50% <P 0> response </> was maintained in 16.8 and 14.6% of galcanezumab-treated patients (120 mg and 240 mg) and was greater than placebo (6.3%; p < 0.001). Few patients maintained >/=75% <P 0> response </>. CONCLUSIONS: Treatment with galcanezumab 120 mg or 240 mg demonstrated statistically significant and clinically meaningful persistence of effect in patients with episodic migraine (>/=3 and 6 consecutive months) and in patients with chronic migraine (for 3 months). STUDY IDENTIFICATION AND TRIAL REGISTRATION: Study Identification: EVOLVE-1 (I5Q-MC-CGAG); EVOLVE-2 (I5Q-MC-CGAH); REGAIN (I5Q-MC-CGAI) TRIAL REGISTRATION: ClinicalTrials.gov ; NCT02614183 (EVOLVE-1); NCT02614196 (EVOLVE-2); NCT02614261 (REGAIN).

30594217\_PD.txt

Title: Cluster randomized evaluation of the Nia Project: study protocol.

Publication Type: Randomized Controlled Trial

Journal-Name:Reproductive health

Journal ID: 101224380

Publication date: 2018/12/31 06:00 [entrez]

BACKGROUND: The onset of puberty and menarche is a specifically vulnerable time for girls, during which they begin to show interest in the opposite sex, while becoming exposed to a myriad of external pressures, including sexual coercion or harassment from boys and men, expectations to marry from their families, and the need to perform well in primary school in order to qualify for secondary school. According to several qualitative studies in Africa, such pressures are exacerbated by girls' lack of knowledge of their bodies, their rights, and the implications of their decisions, and by their inability to manage puberty and adolescence safely and comfortably with appropriate menstrual health and hygiene management (MHM) products. The evaluation of the Nia Project is one of the first to analyze the individual and combined contributions of sanitary pads and provision of comprehensive reproductive health education on girls' <P 33> education </> and <P 0> reproductive health </> outcomes. METHODS: The design for the evaluation of the Nia Project is a longitudinal, cluster-randomized controlled trial consisting of a baseline survey with a cohort of Class 7 girls, a school quality survey, qualitative data collection, school attendance tracking, and an endline survey at the completion of the 18-month intervention period with the same cohort. The study involves 140 public primary schools in three rural sub-counties (Magarini, Kaloleni and Ganze) of Kilifi County in the Coastal area of Kenya. The research sample includes 3489 girls, with about 25 girls per school on average. Before program implementation, the schools were stratified by sub-county and randomized to one of four study arms (35 schools per arm): 1) control, 2) disposable sanitary pads distribution, 2) reproductive health education, and 4) sanitary pad distribution and reproductive health education. DISCUSSION: The evidence provided will inform program investment and design, and contribute to the literature on the effect of menstrual health-based interventions on girls' <P 33> agency </>, safety and <P 33> life </> outcomes. TRIAL REGISTRATION: ISRCTN10894523 . Trial Registration Date: August 22, 2017.

30595271\_PD.txt

Title: Efficacy of RADPAD protection drape in reducing <P 32> radiation exposure </> in the catheterization laboratory-First Indian study.

Publication Type: Randomized Controlled Trial

Journal-Name:Indian heart journal

Journal ID: 0374675

Publication date: 2018/03/27 00:00 [accepted]

BACKGROUND: Occupational radiation exposureis a growing problem due to increasing number and complexity of interventional procedures.The RADPAD is a lead-free sterile drape containing bismuth and barium that reduces scatter radiation during fluoroscopic procedures. We aimed to study the <P 32> radiation exposure </> reduction to operators with the use of RADPAD and also measureradiation doses in different angiographic projections. METHODS: 65 randomly selected patients undergoing elective complex percutaneous coronary intervention (PCI) procedures from January 2017 to 2017 were randomized in a 1:1 pattern with or without the RADPAD. Primary endpoint was the <P 32> ratio of operator received dose {in mrem} to total radiation </> in Gyat the end of the procedure which was designated ''Relative operator exposure'', with or without RADPAD. RESULTS: Despite similar fluoroscopy times (20.4+/-9.4min with RADPAD vs. 19.4+/-9.2min without RADPAD, P=0.871) and total radiation dose (3.4+/-4.3 Gy with RADPAD vs. 2.3+/-1.4 Gy, P=0.198), the <P 32> relative operator exposure </> was significantly less with RADPAD (1.39+/-0.95) as compared to no RADPAD group (2.27+/-1.4) (p=0.004) amounting to a 39% reduction. Additionally mean <P 32> radiation dose </> per shoot of recorded Left anterior oblique (LAO) oriented projections was 34.4+/-15.7mGyvs 24.9+/-12.9 mGy for a non LAO oriented projection. (p<0.001). CONCLUSION: RADPAD significantly reduces <P 32> radiation exposure </> to the primary operator during prolonged complex PCI procedures. Further, amongst all views, LAO views have significantly higher emitted radiation as compared to Non LAO views and need more radiation protection.

30595274\_PD.txt

Title: Heart Rate Variability following Combined Aerobic and Resistance Training in Sedentary Hypertensive Women: A Randomised Control Trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Indian heart journal

Journal ID: 0374675

Publication date: 2018/03/20 00:00 [accepted]

OBJECTIVE: To investigate the effect of combined aerobic and resistance training (CART) on <P 0> heart rate variability </> in sedentary, hypertensive women. PARTICIPANTS: A total of twenty-eight hypertensive (Stage 1 and 2) sedentary women (Age 40.54+/-4.2 yrs; Height 155.14+/-5.4cm; Weight 70.96+/-10.2kg; BMI 29.6+/-4.4; Duration of HTN: 6.43+/-2.5 yrs) were recruited for the study. METHODS: Participants were randomly assigned to either the CART group that performed combined aerobic and resistance exercise of moderate intensity [aerobic exercise 50-80% of HRmax (maximum heart rate) and resistance exercises at 50-80% of 1 Repetition Maximum (RM)], 5 times/week for 4 weeks, or to the control group that followed conventional treatment without any supervised exercise intervention. MAIN OUTCOME MEASURES: <P 0> Resting blood pressure </> was measured and standard <P 0> heart rate variability (HRV) </> indices were calculated using time domain (<P 0> SDNN </>, <P 0> pNN50 </>, <P 0> RMSSD </>) and frequency domain (<P 0> LFnu </>, <P 0> HFnu </>, <P 0> LF/HF </> and <P 0> TP </>) analysis. RESULTS: CART group demonstrated an increase in <P 0> HFnu </>, <P 0> TP </>, <P 0> SDNN </>, and <P 0> RMSSD </>, (p<0.05) along with a significant decrease in <P 0> LFnu </>, <P 0> LF/HF ratio </>, <P 0> systolic blood pressure </>, and <P 0> diastolic blood pressure </> (p<0.05). CONCLUSION: CART showed significant improvement in <P 0> heart rate variability (HRV) </> parameters indicating vagal dominance in middle-aged hypertensive women. Therefore, exercise training in combined form (aerobic and resistance) may be incorporated in the management programs of the patients suffering from hypertension in order to augment improvement in their cardiac autonomic control.

30595283\_PD.txt

Title: Comparison of lower loading dose of prasugrel with conventional loading dose of prasugrel in Indian patients undergoing percutaneous coronary interventions.

Publication Type: Randomized Controlled Trial

Journal-Name:Indian heart journal

Journal ID: 0374675

Publication date: 2018/08/02 00:00 [accepted]

BACKGROUND: Although conventional 60 mg of prasugrel allows for rapid and potent platelet inhibition within 30 min after loading dose, the efficacy and safety of lower doses of prasugrel in Indian patients has not yet been investigated. OBJECTIVE: The study sought to compare the efficacy of a lower loading dose of prasugrel with conventional loading dose of prasugrel in Indian patients. MATERIAL AND METHODS: Three hundred thirty-two Indian patients undergoing elective percutaneous coronary intervention (PCI) were enrolled in the study. Participants were randomly administered loading doses of prasugrel 60 mg (group A, n = 166) or 30 mg (group B, n = 166) before undergoing elective PCI in a 1:1 manner. Primary efficacy end point was composite of <P 1> in-hospital death </> and <P 0> stent thrombosis </> at 96 h, while safety end point was <P 0> in-hospital bleeding </>. RESULTS: The two groups did not differ in their baseline characteristics. The primary efficacy end point was 0.6% in both the conventional 60 mg loading dose (LD) and lower 30 mg LD groups (p = not significant). <P 0> Minor bleeding </> was significantly less in group B [Bleeding Academic Research Consortium 1, A = 6.63% vs B = 1.81%, odds ratio (OR) = 3.86, 95% confidence interval (CI) = 1.06-14.08, P = 0.05]. <P 0> Major bleeding </> was higher in group A (A = 3.61%, vs B = 1.81%, OR = 2.04, 95% CI = 0.50-8.29, P = 0.50). CONCLUSION: In Indian patients, 30 mg of prasugrel loading is as effective as 60 mg of prasugrel with significantly less <P 0> minor bleeding </>.

30595284\_PD.txt

Title: Open-labeled randomized controlled trial to evaluate the 1-year clinical outcomes of polymer-free sirolimus-eluting coronary stents as compared with biodegradable polymer-based sirolimus-eluting coronary stents.

Publication Type: Randomized Controlled Trial

Journal-Name:Indian heart journal

Journal ID: 0374675

Publication date: 2018/08/13 00:00 [accepted]

BACKGROUND: Head to head trials of clinical outcomes of sirolimus eluting polymer free vs. biodegradable polymer stents are lacking. METHODS: Single centre prospective open labeled randomised controlled clinical trial. Basis for sample size calculation was the rate of MACE from the ISAR TEST 3 trial in which the absolute difference was 10.25% with a standard deviation of 0.24. Assuming null hypothesis, 80% power and 5% alpha error, to detect a 10% difference, adjusting for 10% loss of follow up, sample size was 204. INCLUSION CRITERIA: Patients with stable coronary artery disease or recent acute coronary syndrome ( >1 week from the date of STEMI), being taken up for elective angioplasty. END POINTS: Primary end point was <P 0, 1> MACE </> at 1 year and secondary end points at the end of 1 year were <P 1> cardiac death </>, urgent target <P 36> lesion revascularization </>, <P 0> acute coronary syndrome </>, <P 0> stroke </> and <P 0> in-stent re-stenosis </>. RESULTS: 204 patients were enrolled between January 2013 to July 2014, 91 in the polymer-free group and 113 in the biodegradable polymer group. Baseline characteristics were comparable between both groups. 21 patients (10.29%), were lost to follow up. <P 0, 1> MACE </> at 1 year were comparable in both the groups 3 of 85(3.52%) in the polymer-free group and 3 of 98(3.06%) in the biodegradable polymer group, p = 0.859. The secondary end points were also comparable between the two groups- <P 1> Death </> - 1 of 85(1.17%) vs. 2 of 98(2.04%), p = 0.646, <P 0> Stroke </> 0 of 85 vs. 2 of 98(2.04%), p = 0.185 and <P 0> acute coronary syndrome </> - 2 of 85(2.35%) vs. 1 of 98(1.02%), p = 0.204. There were no instances of urgent target <P 36> lesion re-vascularisation </> or definite <P 0> stent thrombosis </> in either groups. <P 0> In stent re-stenosis </> was found in 7 of 85(8.2%) in the polymer-free group vs. 6 of 98(6.12%) in the biodegradable polymer group. CONCLUSION: The 1 year <P 0, 1> MACE </> rates are comparable in patients who underwent elective coronary revascularization using sirolimus eluting polymer-free and biodegradable polymer stents.