30621622\_PD.txt

Title: Preventive effect of ecabet sodium on low-dose aspirin-induced <P 0> small intestinal mucosal injury </>: a randomized, double-blind, pilot study.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC gastroenterology

Journal ID: 100968547

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: We aimed to investigate how high-dose ecabet sodium affects low-dose aspirin-induced small intestinal mucosal injury in healthy volunteers. METHODS: Healthy volunteers were enrolled randomly into one of two groups with the following drug regimens for 2 weeks: group A, low-dose aspirin once per day and group B, low-dose aspirin and 4.0 g of ecabet sodium. Small bowel capsule endoscopy was performed before and 2 weeks after low-dose aspirin administration. RESULTS: A significant difference was found in the median number [range] of <P 0> small intestinal lesions </> between baseline and two weeks after low-dose aspirin administration in group A (baseline: 1 [0-5], after: 5 [1-11]; p = 0.0059) but not in group B (baseline: 0.5 [0-9], after: 3 [0-23]; p = 0.0586). In group B, although the median number [range] of <P 0> lesions </> in the first tertile of the small intestine did not increase two weeks after low-dose aspirin administration (baseline: 0 [0-4], after: 1.5 [0-8]; p = 0.2969), the number of <P 0> lesions </> in the second and third tertiles of the small intestine increased significantly (baseline: 0 [0-5], after: 2 [0-15]; p = 0.0469). CONCLUSIONS: Ecabet sodium had a preventive effect on low-dose aspirin-induced small intestinal mucosal injury in the upper part of the small intestine. TRIAL REGISTRATION: ISRCTN 99322160 , 01/10/2018.

30621653\_PD.txt

Title: Baseline characteristics associated with early <P 0> visual acuity </> gains after ranibizumab treatment for retinal vein occlusion.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC ophthalmology

Journal ID: 100967802

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: To identify baseline patient characteristics associated with early clinically significant <P 0> visual acuity (VA) </> improvements within 3 months of treatment initiation in ranibizumab-treated patients with retinal vein occlusion (RVO) in the SHORE study. METHODS: Post hoc analysis of baseline patient characteristics in the randomized, open-label, vision examiner-masked SHORE phase 4 study that compared monthly versus pro re nata dosing of ranibizumab in patients with branch and central RVO. Patients who enrolled in SHORE fulfilled eligibility criteria per protocol (N = 202). SHORE data were retrospectively analyzed to identify baseline patient characteristics associated with early clinically significant improvements in <P 0> visual acuity (VA) </>, defined as improvement to a Snellen equivalent of 20/40 or better <P 0> vision </> (>/= 69 [T Early Treatment <P 0> Diabetic Retinopathy </> Study (ETDRS)] letters) or an increase in <P 0> best-corrected visual acuity (BCVA) </> of 15 or more ETDRS letters from baseline within 3 months of treatment initiation. Main outcome measures were <P 0> best-corrected visual acuity (BCVA) </> gain of 15 or more ETDRS letters from baseline, Snellen equivalent of 20/40 or better <P 0> vision </>, and baseline factors associated with early clinically significant improvement in <P 0> best-corrected visual acuity (BCVA) </>. RESULTS: The median <P 0> time for patients to achieve a best-corrected visual acuity (BCVA) </> of 20/40 or better was 59 days and the median time for patients to gain 15 or more {[T Early Treatment <P 0> Diabetic Retinopathy </> Study (ETDRS)]} letters was 63 days. Better baseline BCVA (> 50 ETDRS letters/Snellen equivalent >/= 20/100), greater baseline total macular volume (> 9.99 mm(3)), and presence of subretinal fluid at baseline were all associated with early improvement to 20/40 or better <P 0> vision </> ([T Early Treatment <P 0> Diabetic Retinopathy </> Study (ETDRS)] equivalent >/= 69 letters; P < .0001, P = .02, and P = .03, respectively). CONCLUSIONS: This retrospective analysis found that better BCVA, greater total macular volume, and presence of subretinal fluid at baseline were associated with more rapid <P 0> vision </> gains. Clinicians may find these helpful when considering the likelihood of achieving early clinically significant <P 0> visual acuity (VA) </> improvements with ranibizumab in patients with RVO. TRIAL REGISTRATION: ClinicalTrials.gov NCT01277302 .

30621673\_PD.txt

Title: Cost-effectiveness and <P 30> quality of life </> of a diet intervention postpartum: 2-year results from a randomized controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC public health

Journal ID: 100968562

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: Pregnancy has been identified as a contributor to obesity. We have shown that a diet intervention postpartum produced a 2-y weight loss of 8%. Here, we present the impact of the diet intervention on cost-effectiveness and explore changes in <P 30> quality of life (QOL) </>. METHODS: A total of 110 postpartum women with overweight/obesity were randomly assigned to diet (D-group) or control (C-group). D-group received a 12-wk diet intervention within primary health care followed by monthly emails up to the 1-y follow-up. C-group received a brochure. Changes in QOL were measured using the [T 36-item Short Form <P 0> Health </> Survey] and [T EQ-5D]. The analysis of cost-effectiveness was a cost-utility analysis with a health care perspective and included <P 34> costs of intervention </> for stakeholder, quality-adjusted life-years (QALYs) gained and <P 34> savings in health care </>. The likelihood of cost-effectiveness was examined using the net monetary benefit method. RESULTS: The D-group increased their <P 30> quality of life (QOL) </> more than the C-group at 12 wk. and 1 y, with pronounced differences for the dimensions <P 0> general health </> and <P 0, 28> mental health </>, and the <P 28> mental </> component summary score (all p < 0.05). <P 34> Cost </> per gained QALY was 1704-7889 USD. The likelihood for cost-effectiveness, based on a willingness to pay 50,000 USD per QALY, was 0.77-1.00. CONCLUSIONS: A diet intervention that produced clinically relevant postpartum weight loss also resulted in increased <P 30> quality of life (QOL) </> and was cost-effective. TRIAL REGISTRATION: Clinical trials, NCT01949558 , 2013-09-24.

30621717\_PD.txt

Title: <P 0> Treatment response </> to indacaterol/glycopyrronium versus salmeterol/fluticasone in exacerbating COPD patients by gender: a post-hoc analysis in the FLAME study.

Publication Type: Journal Article

Journal-Name:Respiratory research

Journal ID: 101090633

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: The burden of chronic obstructive lung disease (COPD) is increasing in women, with recent evidence suggesting gender differences in disease characteristics and potentially in treatment outcomes. METHODS: FLAME was a 52-week randomized controlled trial in patients with severe-to-very-severe COPD and a history of exacerbations. In this post-hoc analysis, gender-based baseline differences and treatment outcomes between indacaterol/glycopyrronium 110/50 mug once daily (IND/GLY) and salmeterol/fluticasone 50/500 twice daily (SFC) were assessed in terms of rate of <P 0> exacerbations </>, <P 0> time-to-first exacerbation </>, <P 0> lung function </>, <P 0> health </> status, and <P 36> rescue medication use </>. RESULTS: This post-hoc analysis included 2557 men and 805 women. Baseline characteristics differed between genders, with women being younger, having better lung function and more often experiencing >/=2 exacerbations in the previous year. Compared with SFC, IND/GLY treatment was associated with reductions in the annualized rates of moderate/severe <P 0> exacerbations </> (rate ratio [95% CI]: 0.81 [0.73-0.91], 0.89 [0.74-1.07] in men and women, respectively). Similarly, <P 0> time-to-first moderate/severe exacerbation </> was also delayed (hazard ratio [95% CI]: 0.79 [0.70-0.89] and 0.76 [0.63-0.91] in men and women, respectively). Results were similar for all (mild/moderate/severe) <P 0> exacerbations </>. Improvements in <P 0> lung function </>, <P 0> health </> status and <P 36> rescue medication use </> with IND/GLY vs SFC were comparable between men and women. The smaller sample size for women may account for some observed discrepancies in <P 0> treatment responses </>. CONCLUSIONS: Although there were gender differences in baseline characteristics, IND/GLY demonstrated similar trends for <P 0> exacerbation </> prevention and <P 0> lung function </>improvement in men and women with moderate-to-very-severe COPD and a history of exacerbations compared with SFC. Small differences in the effects seen between genders may be attributed to the different sizes of the two groups and need to be further evaluated in randomized trials that are appropriately powered for gender analysis. TRIAL REGISTRATION: Post hoc analysis of the FLAME study. ClinicalTrials.gov number: NCT01782326 . Registered 1 February 2013.

30621718\_PD.txt

Title: The effectiveness of a multidisciplinary intervention strategy for the treatment of symptomatic joint hypermobility in childhood: a randomised, single Centre parallel group trial (The Bendy Study).

Publication Type: Randomized Controlled Trial

Journal-Name:Pediatric rheumatology online journal

Journal ID: 101248897

Publication date: 2019/01/10 06:00 [entrez]

INTRODUCTION: Joint hypermobility is common in childhood and can be associated with musculoskeletal pain and dysfunction. Current management is delivered by a multidisciplinary team, but evidence of effectiveness is limited. This clinical trial aimed to determine whether a structured multidisciplinary, multisite intervention resulted in improved clinical outcomes compared with standard care. METHOD: A prospective randomised, single centre parallel group trial comparing an 8-week individualised multidisciplinary intervention programme (bespoke physiotherapy and occupational therapy in the clinical, home and school environment) with current standard management (advice, information and therapy referral if deemed necessary). The primary endpoint of the study was between group difference in child reported <P 0> pain </> from baseline to 12 months as assessed using the [T Wong Baker faces <P 0> pain </> scale]. Secondary endpoints were parent reported <P 0> pain </> (100 mm visual analogue scale), parent reported <P 25> function </> ([T child <P 0> health </> assessment questionnaire]), child reported <P 30> quality of life </> ([T child <P 0> health </> utility 9-dimensional assessment]), <P 25> coordination </> ([T <P 25> movement </> assessment battery for children version 2]) and <P 25> grip strength </> (handheld dynamometer). RESULTS: 119 children aged 5 to 16 years, with symptomatic hypermobility were randomised to receive an individualised multidisciplinary intervention (I) (n = 59) or standard management (S) (n = 60). Of these, 105 completed follow up at 12 months. No additional significant benefit could be shown from the intervention compared to standard management. However, there was a statistically significant improvement in child and parent reported <P 0> pain </>, <P 25> coordination </> and <P 25> grip strength </> in both groups. The response was independent of the degree of hypermobility. CONCLUSION: This is the first randomised controlled trial to compare a structured multidisciplinary, multisite intervention with standard care in symptomatic childhood hypermobility. For the majority, the provision of education and positive interventions aimed at promoting healthy exercise and self-management was associated with significant benefit without the need for more complex interventions. TRIAL REGISTRATION: The trial was registered prospectively with the national database at the Clinical Research Network (UKCRN Portfolio 9366). The trial was registered retrospectively with ISRCTN ( ISRCTN86573140 ).

30621733\_PD.txt

Title: The effects of position on <P 0> gastric residual volume </> of premature infants in NICU.

Publication Type: Randomized Controlled Trial

Journal-Name:Italian journal of pediatrics

Journal ID: 101510759

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: Nutrition cares are of the main measures to save premature infants. In this regard, proper positioning is one of the key measures that is done by nurses; still there is a paucity of studies in this field and the results of these few studies are an area of ongoing debates. In light of this, the present paper is an attempt to determine the effects of different positioning on <P 0> gastric residual volume </> in premature infants in NICU. METHODS: A clinical trial cross-over study was carried out on premature infants in NICU. The subjects, who had inclusion criteria, were selected through convenience sampling based on inclusion criteria and randomly allocated into three groups. <P 0> Gastric residual volume </> before and one hours after feeding was measured and recorded for three positions including right-lateral, left-lateral, and prone. The data was analyzed via SPSS-21 using descriptive statistics such as mean, standard deviation, and frequency; and inferential statistics such as Chi Squared, Kruskal Wallis test, and Friedman test. RESULTS: Totally, 135 infants in three groups were studied and the results showed that minimum and maximum <P 0> gastric residual volumes </> were in prone (6.49 +/- 8.25 ML) and supine (12.59 +/- 11.9 ML) positions, respectively. However, Kruskal Wallis test did not show a significant relationship between the three positions under study and the mean <P 0> gastric residual volume </>. CONCLUSION: Prone position was featured with the lowest <P 0> gastric residual volume </> and highest possibility of <P 0> absorbing nutrient </>. Still, given the fact that no significant difference was found in the three groups, further and deeper studies are needed. TRIAL REGISTRATION: The project is approved by Iranian Registry of Clinical Trial with no. IRCT. 201404134736 N6 .

30621791\_PD.txt

Title: Wellbeing intervention for chronic kidney disease (WICKD): a randomised controlled trial study protocol.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC psychology

Journal ID: 101627676

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: Incidence of end stage kidney disease (ESKD) for Indigenous Australians is especially high in remote and very remote areas of Australia (18 and 20 times the rate of comparable non-Indigenous people). Relocating away from family and country for treatment, adjusting to life with a chronic condition and time lost to dialysis cause grief and sadness which have immense impact on quality of life and challenges treatment adherence. We describe the first randomised controlled trial to address both chronic disease and mental health in Indigenous people with ESKD, which is the first to test the effectiveness of a culturally adapted e-mental health intervention in this population. It builds on an existing program of mental health research with demonstrated efficacy - the Aboriginal and Islander Mental Health Initiative (AIMhi) - to test the newly developed electronic motivational care planning (MCP) therapy - the AIMhi Stay Strong App. METHODS: This is a 3-arm, waitlist, single-blind randomised controlled trial testing the efficacy of the Stay Strong App in improving <P 28> psychological distress </>, <P 0, 28> depressive symptoms </>, <P 30> quality of life </> and <P 32> treatment adherence </> among Indigenous clients undergoing haemodialysis for ESKD in Alice Springs and Darwin with follow up over two periods of 3 months (total of 6 months observation). The study compares the efficacy of MCP using the AIMhi Stay Strong App with two control groups (control app intervention and treatment as usual) on participant-reported <P 28> psychological distress </> (the primary outcome) using the [T Kessler Distress Scale (K10)]; <P 0, 28> depressive symptoms </> using the adapted [T Patient <P 0> Health </> Questionnaire (PHQ-9)]; <P 30> quality of life </> using the EuroQoL instrument ([T EQ5D]) and <P 32> adherence </> to dialysis treatment planning through file audit. Participants are randomised to receive MCP either at baseline (early treatment) or after 3 months (delayed treatment). The study also examines the cost effectiveness of this therapy in this setting through examination of health care service utilisation across groups during the first 3 months. DISCUSSION: This project will contribute much needed evidence on the efficacy of an electronic wellbeing intervention for Indigenous people with ESKD - a group in which distress is likely to be unacceptably high, yet relatively untreated. TRIAL REGISTRATION: Australian New Zealand Clinical Trial Registry; ACTRN12617000249358 ; Date registered: 17/02/2017.

*30624175\_PD.txt*

*Title: Examining diabetic heel ulcers through an ecological lens: microbial community dynamics associated with healing and infection.*

*Publication Type: Randomized Controlled Trial*

*Journal-Name:Journal of medical microbiology*

*Journal ID: 0224131*

*Publication date: 2019/01/10 06:00 [entrez]*

*PURPOSE: While some micro-organisms, such as Staphylococcus aureus, are clearly implicated in causing tissue damage in diabetic foot ulcers (DFUs), our knowledge of the contribution of the entire microbiome to clinical outcomes is limited. We profiled the microbiome of a longitudinal sample series of 28 people with diabetes and DFUs of the heel in an attempt to better characterize the relationship between healing, infection and the microbiome. METHODOLOGY: In total, 237 samples were analysed from 28 DFUs, collected at fortnightly intervals for 6 months or until healing. Microbiome profiles were generated by 16S rRNA gene sequence analysis, supplemented by targeted nanopore sequencing.Result/Key findings. DFUs which failed to heal during the study period (20/28, 71.4 %) were more likely to be persistently colonized with a heterogeneous community of micro-organisms including anaerobes and Enterobacteriaceae (log-likelihood ratio 9.56, P=0.008). During clinically apparent infection, a reduction in the diversity of micro-organisms in a DFU was often observed due to expansion of one or two taxa, with recovery in diversity at resolution. Modelling of the predicted species interactions in a single DFU with high diversity indicated that networks of metabolic interactions may exist that contribute to the formation of stable communities. CONCLUSION: Longitudinal profiling is an essential tool for improving our understanding of the microbiology of chronic wounds, as community dynamics associated with clinical events can only be identified by examining changes over multiple time points. The development of complex communities, particularly involving Enterobacteriaceae and strict anaerobes, may be contributing to poor outcomes in DFUs and requires further investigation.*

30625052\_PD.txt

Title: Hybrid Minimally Invasive Esophagectomy for Esophageal Cancer.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/17 06:00 [medline]

BACKGROUND: Postoperative <P 38> complications </>, especially <P 0> pulmonary complications </>, affect more than half the patients who undergo open esophagectomy for esophageal cancer. Whether hybrid minimally invasive esophagectomy results in lower morbidity than open esophagectomy is unclear. METHODS: We performed a multicenter, open-label, randomized, controlled trial involving patients 18 to 75 years of age with resectable cancer of the middle or lower third of the esophagus. Patients were randomly assigned to undergo transthoracic open esophagectomy (open procedure) or hybrid minimally invasive esophagectomy (hybrid procedure). Surgical quality assurance was implemented by the credentialing of surgeons, standardization of technique, and monitoring of performance. Hybrid surgery comprised a two-field abdominal-thoracic operation (also called an Ivor-Lewis procedure) with laparoscopic gastric mobilization and open right thoracotomy. The primary end point was intraoperative or postoperative <P 38> complication </> of grade II or higher according to the Clavien-Dindo classification (indicating major <P 38> complication </> leading to intervention) within 30 days. Analyses were done according to the intention-to-treat principle. RESULTS: From October 2009 through April 2012, we randomly assigned 103 patients to the hybrid-procedure group and 104 to the open-procedure group. A total of 312 <P 38> serious adverse events </> were recorded in 110 patients. A total of 37 patients (36%) in the hybrid-procedure group had a major intraoperative or postoperative <P 38> complication </>, as compared with 67 (64%) in the open-procedure group (odds ratio, 0.31; 95% confidence interval [CI], 0.18 to 0.55; P<0.001). A total of 18 of 102 patients (18%) in the hybrid-procedure group had a major <P 0> pulmonary complication </>, as compared with 31 of 103 (30%) in the open-procedure group. At 3 years, <P 1> overall survival </> was 67% (95% CI, 57 to 75) in the hybrid-procedure group, as compared with 55% (95% CI, 45 to 64) in the open-procedure group; <P 0, 1> disease-free Survival </> was 57% (95% CI, 47 to 66) and 48% (95% CI, 38 to 57), respectively. CONCLUSIONS: We found that hybrid minimally invasive esophagectomy resulted in a lower incidence of intraoperative and postoperative major <P 38> complications </>, specifically <P 0> pulmonary complications </>, than open esophagectomy, without compromising <P 1>(E1) overall and <P 0, 1> disease-free survival </> over a period of 3 years. (Funded by the French National Cancer Institute; ClinicalTrials.gov number, NCT00937456 .).

30625070\_PD.txt

Title: Caplacizumab Treatment for Acquired Thrombotic Thrombocytopenic Purpura.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/10 06:00 [entrez]

BACKGROUND: In acquired thrombotic thrombocytopenic purpura (TTP), an immune-mediated deficiency of the von Willebrand factor-cleaving protease ADAMTS13 allows unrestrained adhesion of von Willebrand factor multimers to platelets and microthrombosis, which result in thrombocytopenia, hemolytic anemia, and tissue ischemia. Caplacizumab, an anti-von Willebrand factor humanized, bivalent *variable-domain-only immunoglobulin fragment, inhibits interaction between von Willebrand factor multimers and platelets. METHODS: In this double-blind, controlled* trial, we randomly assigned 145 patients with TTP to receive caplacizumab (10-mg intravenous loading bolus, followed by 10 mg daily subcutaneously) or placebo during plasma exchange and for 30 days thereafter. The primary outcome was the <P 0> time to normalization of the platelet count </>, with discontinuation of daily plasma exchange within 5 days thereafter. Key secondary outcomes included a composite of <P 1> TTP-related death </>, <P 0> recurrence </> of TTP, or a <P 0> thromboembolic event </> during the trial treatment period; <P 0> recurrence </> of TTP at any time during the trial; <P 0> refractory TTP </>; and <P 0> normalization of organ-damage </> markers. RESULTS: The median <P 0> time to normalization of the platelet count </> was shorter with caplacizumab than with placebo (2.69 days [95% confidence interval {CI}, 1.89 to 2.83] vs. 2.88 days [95% CI, 2.68 to 3.56], P=0.01), and patients who received caplacizumab were 1.55 times as likely to have a <P 0> normalization of the platelet count </> as those who received placebo. The percentage of patients with a composite outcome event was 74% lower with caplacizumab than with placebo (12% vs. 49%, P<0.001). The percentage of patients who had a <P 0> recurrence </> of TTP at any time during the trial was 67% lower with caplacizumab than with placebo (12% vs. 38%, P<0.001). <P 0> Refractory disease </> developed in no patients in the caplacizumab group and in three patients in the placebo group. Patients who received caplacizumab needed less <P 36> plasma exchange </> and had a shorter <P 35> hospitalization </> than those who received placebo. The most common <P 38> adverse event </> was <P 0> mucocutaneous bleeding </>, which was reported in 65% of the patients in the caplacizumab group and in 48% in the placebo group. During the trial treatment period, three patients in the placebo group <P 1> died </>. One patient in the caplacizumab group <P 1> died </> from cerebral ischemia after the end of the treatment period. CONCLUSIONS: Among patients with TTP, treatment with caplacizumab was associated with faster <P 0> normalization of the platelet count </>; a lower incidence of a composite of <P 1> TTP-related death </>, <P 0> recurrence </> of TTP, or a <P 0> thromboembolic event </> during the trial treatment period; and a lower rate of <P 0> recurrence </> of TTP during the trial than placebo. (Funded by Ablynx; HERCULES ClinicalTrials.gov number, NCT02553317 .).