30683825\_PD.txt

Title: The influence of orlistat, metformin and diet on serum levels of <P 0> insulin-like growth factor-1 </> in obeses women with and without insulin resistance.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of physiology and pharmacology : an official journal of the Polish Physiological Society

Journal ID: 9114501

Publication date: 2019/01/27 06:00 [entrez]

A range of studies showed confusing data about the relationship between obesity, weight reduction and circulating total insulin-like growth factor -1 (IGF-1). The aim of the study was to compare the influence of orlistat (IO), metformin (IM), or calorie-restricted diet (LC) on <P 0> insulin-like growth factor-1 </>, with special respect to insulin-resistance status. One hundred and fourteen obese women aged from 18 to 40 years were divided into insulin sensitive (IS) and insulin resistant (IR) groups and received a low calorie diet (LC), or an isocaloric diet and 500 mg metformin twice daily (IM), or isocaloric diet with 120 mg orlistat three times daily (IO). Before and after the intervention <P 0> anthropometric </> parameters, serum <P 0> lipid </> profile, serum concentrations of <P 0> alanine aminotransferase </>, <P 0> aspartate aminotransferase </>, <P 0> insulin </>, <P 0> glucose </>, <P 0> insulin-like growth factor-1 </>, <P 0> HOMA-IR </> (homeostatic model assessment), and <P 0> visceral adiposity </> index (VAI), and their changes were registered. Although the reductions in <P 0> weight </> and <P 0> body fat </> were comparable in IS and IR groups, only women with IR showed a significant increase in <P 0> insulin-like growth factor-1 </> concentration as a result of all interventions. We found significant positive correlations of Delta <P 0> insulin-like growth factor-1 </> with initial and Delta values of: <P 0> HOMA-IR </>, <P 0> triglyceride/high-density cholesterol ratio </>, <P 0> visceral adiposity </> index (VAI). IR premenopausal women show significant increase in <P 0> insulin-like growth factor-1 </> serum concentrations regardless the method of intervention. The increase in <P 0> insulin-like growth factor-1 </> was parallel to the improvement of <P 0> insulin resistance </> parameters.

30683848\_PD.txt

Title: The effect of different sources of fish and camelina sativa oil on immune cell and adipose tissue <P 0> mRNA expression </> in subjects with abnormal fasting glucose metabolism: a randomized controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrition & diabetes

Journal ID: 101566341

Publication date: 2018/11/20 00:00 [revised]

BACKGROUND/OBJECTIVES: Molecular mechanisms linking fish and vegetable oil intakes to their healthy metabolic effects may involve attenuation of inflammation. Our primary aim was to examine in a randomized controlled setting whether diets enriched in fatty fish (FF), lean fish (LF) or ALA-rich camelina sativa oil (CSO) differ in their effects on the <P 0> mRNA expression </> response of selected inflammation-related genes in peripheral blood mononuclear cells (PBMCs) and subcutaneous adipose tissue (SAT) in subjects with impaired fasting glucose. SUBJECTS/METHODS: Samples from 72 participants randomized to one of the following 12-week intervention groups, FF (n = 19), LF (n = 19), CSO (n = 17) or a control group (n = 17), were available for the PBMC study. For SAT, 39 samples (n = 8, n = 10, n = 9, n = 12, respectively) were available. The <P 0> mRNA expression </> was measured at baseline and 12 weeks by TaqMan(R) Low Density Array. RESULTS: In PBMCs, LF decreased ICAM1 <P 0> mRNA expression </> (P < 0.05), which was different (P = 0.06, Bonferroni correction) from the observed increase in the FF group (P < 0.05). Also, compared to the control group, LF decreased ICAM1 <P 0> mRNA expression </> (P < 0.05). Moreover, the change in ICAM1 <P 0> mRNA expression </> correlated positively with the intake of FF (P < 0.05) and negatively with the intake of LF (P < 0.05), independently of study group. A diet enriched in CSO, a rich source of alpha-linolenic acid (ALA), decreased PBMC IFNG <P 0> mRNA expression </> (P < 0.01). The intake of CSO in the CSO group, but not the increase in plasma ALA proportions, correlated inversely with the IFNG <P 0> mRNA expression </> in PBMCs (P = 0.08). In SAT, when compared with the control group, the effect of FF on decreasing IL1RN <P 0> mRNA expression </> was significant (P < 0.03). CONCLUSION: We propose that CSO intake may partly exert its benefits through immuno-inflammatory molecular regulation in PBMCs, while modulation of ICAM1 expression, an endothelial/vascular-related gene, may be more dependent on the type of fish consumed.

30684970\_PD.txt

Title: Low dose human chorionic gonadotropin administration at the time of gonadotropin releasing-hormone agonist trigger versus 35 h later in women at high risk of developing ovarian hyperstimulation syndrome - a prospective randomized double-blind clinical trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of ovarian research

Journal ID: 101474849

Publication date: 2019/01/28 06:00 [entrez]

BACKGROUND: Ovarian hyperstimulation syndrome remains a serious complication during in vitro fertilization cycles if high dose human chorionic gonadotropin (hCG) is used to trigger ovulation in high responder patients. Though much of this risk is mitigated with trigger using gonadotropin releasing-hormone (GnRH) agonist alone, it may result in lower birth rates. GnRH-agonist trigger and adjuvant low dose hCG has been proposed to improve birth rates, but timing of this hCG support to corpus luteum function has never been fully described. In this randomized, prospective trial, we explore differences in <P 1> live birth </> rates and incidence of <P 0> ovarian hyperstimulation syndrome (OHSS) </> in high-responder patients undergoing in vitro fertilization (IVF) receiving low dose hCG at the time of GnRH-agonist (dual trigger) or hCG adjuvant at the time of oocyte retrieval. Does the timing of hCG support make a difference? RESULTS: Thirty-four subjects high-responder patients were randomized to receive low-dose hCG at the time of GnRH-agonist trigger (Group 1) and 37 received low-dose hCG at the time of oocyte retrieval (Group 2). There were no differences in the baseline characteristics and outcome of ovarian stimulation between the two groups. There were no differences in the <P 1> live birth </> rates between Group 1 and Group 2 by intention-to-treat (14/34, 41.2% versus 21/37, 56.8%, p = 0.19) or per-protocol (14/26, 53.8% versus 19/31, 61.3%, p = 0.57) analyses. There was a slightly higher incidence of <P 0> ovarian hyperstimulation syndrome (OHSS) </> in Group 2 compared to Group 1 although the difference was not statistically significant (3/31, 9.7% versus 1/26, 3.8%). All the cases of OHSS in Group 2 were moderate while the one case of OHSS in Group 1 was mild. CONCLUSIONS: For high responder patients receiving GnRH-agonist trigger, low dose hCG supplementation allowed high <P 0> pregnancy </> rates after fresh embryo transfer, regardless of whether it was given at the time of trigger or at oocyte retrieval. Dual trigger may be preferable to reduce the risk of OHSS.

30688979\_PD.txt

Title: Effect of Intensive vs Standard Blood Pressure Control on Probable <P 0, 29> Dementia </>: A Randomized Clinical Trial.

Publication Type: Journal Article

Journal-Name:JAMA

Journal ID: 7501160

Publication date: 2019/01/29 06:00 [entrez]

Importance: There are currently no proven treatments to reduce the risk of mild cognitive impairment and dementia. Objective: To evaluate the effect of intensive blood pressure control on risk of <P 0, 29> dementia </>. Design, Setting, and Participants: Randomized clinical trial conducted at 102 sites in the United States and Puerto Rico among adults aged 50 years or older with hypertension but without diabetes or history of stroke. Randomization began on November 8, 2010. The trial was stopped early for benefit on its primary outcome (a composite of <P 0> cardiovascular </> events) and <P 1> all-cause mortality </> on August 20, 2015. The final date for follow-up of cognitive outcomes was July 22, 2018. Interventions: Participants were randomized to a systolic blood pressure goal of either less than 120 mm Hg (intensive treatment group; n = 4678) or less than 140 mm Hg (standard treatment group; n = 4683). Main Outcomes and Measures: The primary cognitive outcome was occurrence of adjudicated probable <P 0, 29> dementia </>. Secondary cognitive outcomes included adjudicated mild <P 29> cognitive impairment </> and a composite outcome of mild <P 0, 29> cognitive impairment or probable dementia </>. Results: Among 9361 randomized participants (mean age, 67.9 years; 3332 women [35.6%]), 8563 (91.5%) completed at least 1 follow-up cognitive assessment. The median intervention period was 3.34 years. During a total median follow-up of 5.11 years, adjudicated probable <P 0, 29> dementia </> occurred in 149 participants in the intensive treatment group vs 176 in the standard treatment group (7.2 vs 8.6 cases per 1000 person-years; hazard ratio [HR], 0.83; 95% CI, 0.67-1.04). Intensive BP control significantly reduced the risk of mild <P 29> cognitive impairment </> (14.6 vs 18.3 cases per 1000 person-years; HR, 0.81; 95% CI, 0.69-0.95) and the combined rate of mild <P 0, 29> cognitive impairment or probable dementia </> (20.2 vs 24.1 cases per 1000 person-years; HR, 0.85; 95% CI, 0.74-0.97). Conclusions and Relevance: Among ambulatory adults with hypertension, treating to a systolic blood pressure goal of less than 120 mm Hg compared with a goal of less than 140 mm Hg did not result in a significant reduction in the risk of probable <P 0, 29> dementia </>. Because of early study termination and fewer than expected cases of dementia, the study may have been underpowered for this end point. Trial Registration: ClinicalTrials.gov Identifier: NCT01206062.

30695089\_PD.txt

Title: Three-Year Prospective Randomized Comparative Assessment of Anterior Maxillary Single Implants with Different Abutment Interfaces.

Publication Type: Journal Article

Journal-Name:The International journal of oral & maxillofacial implants

Journal ID: 8611905

Publication date: 2019/03/05 06:00 [medline]

PURPOSE: The goal of this investigation was to define time-dependent <P 0> peri-implant tissue </> changes at implants with different abutment interface designs. MATERIALS AND METHODS: Participants requiring replacement of single maxillary anterior and first premolar teeth were recruited and treated under an institutional review board (IRB)-approved protocol. Implants, titanium abutments, and provisional crowns were placed in healed ridges 5 months following preservation after tooth extraction with recombinant human bone morphogenetic protein-2 (rhBMP-2). Twelve weeks later, permanent crowns were placed on patient-specific abutments and evaluated at 6, 12, and 36 months following implant placement. Clinical and radiographic assessments of <P 0> abutments </> and <P 0> crowns </>, <P 0> peri-implant mucosa </>, and <P 0> marginal bone </> levels were recorded. RESULTS: The 3-year assessment included 45 conical interface (CI), 34 flat-to-flat interface (FI), and 32 platform-switched interface (PS) implants in 111 participants. At 3 years, the mean <P 0> marginal bone </> level (MBL) change at CI, FI, and PS implants was -0.12, -1.02, and -1.04 mm, respectively (P = .014). "Zero" <P 0> marginal bone </> level (MBL) loss or gain was measured over the 3-year period at 72.1% CI, 3.0% FI, and 16.6% PS implants. There was a minor change (0.0 to 0.3 mm) in <P 0> peri-implant mucosal zenith positions </> over time and between groups. Eighty percent of CI implants, 61% of FI implants, and 84% of PS implants were observed to have a clinically stable <P 0> peri-implant mucosal zenith position </> with less than 0.5 mm of measured recession. Over the 36-month period, there were no significant changes in the <P 0> location of mesial or distal papilla </> in any group. CONCLUSION: Significant differences in MBLs were observed at different implant interfaces. Conical implant interfaces, but not flat-to-flat or platform-switched implant interfaces, were associated with no <P 0> marginal bone </> level (MBL) changes over 3 years. Peri-implant mucosal stability was generally observed. The relationship of marginal bone responses and peri-implant mucosal stability requires further evaluation.

30696423\_PD.txt

Title: High-intensity interval training and moderate-intensity continuous training in adults with Crohn's disease: a pilot randomised controlled trial.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC gastroenterology

Journal ID: 100968547

Publication date: 2019/01/31 06:00 [entrez]

BACKGROUND: This study assessed the <P 32> feasibility </> and <P 32> acceptability </> of two common types of exercise training-high-intensity interval training (HIIT) and moderate-intensity continuous training (MICT)-in adults with Crohn's disease (CD). METHODS: In this mixed-methods pilot trial, participants with quiescent or mildly-active CD were randomly assigned 1:1:1 to HIIT, MICT or usual care control, and followed up for 6 months. The HIIT and MICT groups were offered three exercise sessions per week for the first 12 weeks. <P 32> Feasibility </> outcomes included rates of <P 32> recruitment </>, <P 32> retention </>, <P 32> outcome completion </>, and <P 32> exercise attendance </>. Data were collected on <P 0> cardiorespiratory fitness </> (e.g., <P 0> peak oxygen uptake </>), <P 0> disease activity </>, <P 0> fatigue </>, <P 30> quality of life </>, <P 38> adverse events </>, and intervention <P 32> acceptability </> (via interviews). RESULTS: Over 17 months, 53 patients were assessed for eligibility and 36 (68%) were randomised (47% male; mean age 36.9 [SD 11.2] years); 13 to HIIT, 12 to MICT, and 11 to control. The exercise session <P 32> attendance </> rate was 62% for HIIT (288/465) and 75% for MICT (320/429), with 62% of HIIT participants (8/13) and 67% of MICT participants (8/12) completing at least 24 of 36 sessions. One participant was <P 32> lost to follow-up </>. <P 32> Outcome completion </> rates ranged from 89 to 97%. The mean increase in <P 0> peak oxygen uptake </>, relative to control, was greater following HIIT than MICT (2.4 vs. 0.7 mL/kg/min). There were three non-serious exercise-related <P 38> adverse events </>, and two exercise participants experienced <P 0> disease relapse </> during follow-up. CONCLUSIONS: The findings support the <P 32> feasibility </> and <P 32> acceptability </> of the exercise programmes and trial procedures. A definitive trial is warranted. Physical exercise remains a potentially useful adjunct therapy in CD. [ID: ISRCTN13021107].

30699054\_PD.txt

Title: A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/01/31 06:00 [entrez]

BACKGROUND: E-cigarettes are commonly used in attempts to stop smoking, but evidence is limited regarding their effectiveness as compared with that of nicotine products approved as smoking-cessation treatments. METHODS: We randomly assigned adults attending U.K. National Health Service stop-smoking services to either nicotine-replacement products of their choice, including product combinations, provided for up to 3 months, or an e-cigarette starter pack (a second-generation refillable e-cigarette with one bottle of nicotine e-liquid [18 mg per milliliter]), with a recommendation to purchase further e-liquids of the flavor and strength of their choice. Treatment included weekly behavioral support for at least 4 weeks. The primary outcome was sustained <P 0> abstinence </> for 1 year, which was validated biochemically at the final visit. Participants who were lost to follow-up or did not provide biochemical validation were considered to not be abstinent. Secondary outcomes included participant-reported <P 32> treatment usage </> and <P 0> respiratory symptoms </>. RESULTS: A total of 886 participants underwent randomization. The 1-year <P 0> abstinence </> rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group (relative risk, 1.83; 95% confidence interval [CI], 1.30 to 2.58; P<0.001). Among participants with 1-year abstinence, those in the e-cigarette group were more likely than those in the nicotine-replacement group to <P 32> use their assigned product </> at 52 weeks (80% [63 of 79 participants] vs. 9% [4 of 44 participants]). Overall, <P 0> throat or mouth irritation </> was reported more frequently in the e-cigarette group (65.3%, vs. 51.2% in the nicotine-replacement group) and <P 0> nausea </> more frequently in the nicotine-replacement group (37.9%, vs. 31.3% in the e-cigarette group). The e-cigarette group reported greater declines in the incidence of <P 0> cough </> and <P 0> phlegm production </> from baseline to 52 weeks than did the nicotine-replacement group (relative risk for cough, 0.8; 95% CI, 0.6 to 0.9; relative risk for phlegm, 0.7; 95% CI, 0.6 to 0.9). There were no significant between-group differences in the incidence of <P 0> wheezing </> or <P 0> shortness of breath </>. CONCLUSIONS: E-cigarettes were more effective for <P 0> smoking cessation </> than nicotine-replacement therapy, when both products were accompanied by behavioral support. (Funded by the National Institute for Health Research and Cancer Research UK; Current Controlled Trials number, ISRCTN60477608 .).

30699314\_PD.txt

Title: Bilateral versus Single Internal-Thoracic-Artery Grafts at 10 Years.

Publication Type: Journal Article

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/02/09 06:00 [medline]

BACKGROUND: Multiple arterial grafts may result in longer survival than single arterial grafts after coronary-artery bypass grafting (CABG) surgery. We evaluated the use of bilateral internal-thoracic-artery grafts for CABG. METHODS: We randomly assigned patients scheduled for CABG to undergo bilateral or single internal-thoracic-artery grafting. Additional arterial or vein grafts were used as indicated. The primary outcome was <P 1> death from any cause </> at 10 years. The composite of <P 1> death from any cause </>, <P 0> myocardial infarction </>, or <P 0> stroke </> was a secondary outcome. RESULTS: A total of 1548 patients were randomly assigned to undergo bilateral internal-thoracic-artery grafting (the bilateral-graft group) and 1554 to undergo single internal-thoracic-artery grafting (the single-graft group). In the bilateral-graft group, 13.9% of the patients received only a single internal-thoracic-artery graft, and in the single-graft group, 21.8% of the patients also received a radial-artery graft. Vital status was not known for 2.3% of the patients at 10 years. In the intention-to-treat analysis at 10 years, there were 315 <P 1> deaths </> (20.3% of the patients) in the bilateral-graft group and 329 deaths (21.2%) in the single-graft group (hazard ratio, 0.96; 95% confidence interval [CI], 0.82 to 1.12; P=0.62). Regarding the composite outcome of <P 1> death </>, <P 0> myocardial infarction </>, or <P 0> stroke </>, there were 385 patients (24.9%) with an event in the bilateral-graft group and 425 patients (27.3%) with an event in the single-graft group (hazard ratio, 0.90; 95% CI, 0.79 to 1.03). CONCLUSIONS: Among patients who were scheduled for CABG and had been randomly assigned to undergo bilateral or single internal-thoracic-artery grafting, there was no significant between-group difference in the rate of <P 1> death from any cause </> at 10 years in the intention-to-treat analysis. Further studies are needed to determine whether multiple arterial grafts provide better outcomes than a single internal-thoracic-artery graft. (Funded by the British Heath Foundation and others; Current Controlled Trials number, ISRCTN46552265 .).

30699315\_PD.txt

Title: Oral versus Intravenous Antibiotics for Bone and Joint Infection.

Publication Type: Equivalence Trial

Journal-Name:The New England journal of medicine

Journal ID: 0255562

Publication date: 2019/02/09 06:00 [medline]

BACKGROUND: The management of complex orthopedic infections usually includes a prolonged course of intravenous antibiotic agents. We investigated whether oral antibiotic therapy is noninferior to intravenous antibiotic therapy for this indication. METHODS: We enrolled adults who were being treated for bone or joint infection at 26 U.K. centers. Within 7 days after surgery (or, if the infection was being managed without surgery, within 7 days after the start of antibiotic treatment), participants were randomly assigned to receive either intravenous or oral antibiotics to complete the first 6 weeks of therapy. Follow-on oral antibiotics were permitted in both groups. The primary end point was definitive <P 0> treatment failure </> within 1 year after randomization. In the analysis of the risk of the primary end point, the noninferiority margin was 7.5 percentage points. RESULTS: Among the 1054 participants (527 in each group), end-point data were available for 1015 (96.3%). <P 0> Treatment failure </> occurred in 74 of 506 participants (14.6%) in the intravenous group and 67 of 509 participants (13.2%) in the oral group. Missing end-point data (39 participants, 3.7%) were imputed. The intention-to-treat analysis showed a difference in the risk of definitive <P 0> treatment failure </> (oral group vs. intravenous group) of -1.4 percentage points (90% confidence interval [CI], -4.9 to 2.2; 95% CI, -5.6 to 2.9), indicating noninferiority. Complete-case, per-protocol, and sensitivity analyses supported this result. The between-group difference in the incidence of <P 38> serious adverse events </> was not significant (146 of 527 participants [27.7%] in the intravenous group and 138 of 527 [26.2%] in the oral group; P=0.58). Catheter <P 38> complications </>, analyzed as a secondary end point, were more common in the intravenous group (9.4% vs. 1.0%). CONCLUSIONS: Oral antibiotic therapy was noninferior to intravenous antibiotic therapy when used during the first 6 weeks for complex orthopedic infection, as assessed by <P 0> treatment failure </> at 1 year. (Funded by the National Institute for Health Research; OVIVA Current Controlled Trials number, ISRCTN91566927 .).

30700116\_PD.txt

Title: A randomized, double-blind, placebo-controlled trial on the efficacy of tranexamic acid combined with rivaroxaban thromboprophylaxis in reducing <P 0> blood loss </> after primary cementless total hip arthroplasty.

Publication Type: Journal Article

Journal-Name:The bone & joint journal

Journal ID: 101599229

Publication date: 2019/02/01 06:01 [medline]

AIMS: Cementless primary total hip arthroplasty (THA) is associated with risks of bleeding and thromboembolism. Anticoagulants are effective as venous thromboprophylaxis, but with an increased risk of bleeding. Tranexamic acid (TXA) is an efficient antifibrinolytic agent, but the mode and timing of its administration remain controversial. This study aimed to determine whether two intravenous (IV) TXA regimens (a three-hour two-dose (short-TXA) and 11-hour four-dose (long-TXA)) were more effective than placebo in reducing perioperative real <P 0> blood loss </> (RBL, between baseline and day 3 postoperatively) in patients undergoing THA who receive rivaroxaban as thromboprophylaxis. The secondary aim was to assess the non-inferiority of the reduction of <P 0> blood loss </> of the short protocol versus the long protocol. PATIENTS AND METHODS: A multicentre, prospective, randomized, double-blind, placebo-controlled trial was undertaken involving 229 patients undergoing primary cementless THA using a posterior approach, whose extended rivaroxaban thromboprophylaxis started on the day of surgery. There were 98 male and 131 female patients, with a mean age of 65.5 years (32 to 91). The primary outcome, perioperative real <P 0> blood loss </> (RBL), was evaluated at 72 hours postoperatively. The efficacy of short- and long-TXA protocols in the reduction of perioperative real <P 0> blood loss </> (RBL) was compared with a placebo group. RESULTS: TXA significantly reduced perioperative <P 0> blood loss </> compared with placebo (p < 0.001); the mean differences were 525.3 ml (short-TXA vs placebo) and 550.1 ml (long-TXA vs placebo). No <P 0> venous or arterial thromboembolic complications </> were reported. The upper boundary of the 95% confidence interval, when comparing short and long protocols, was below the pre-specified margin of non-inferiority (p = 0.027). CONCLUSION: In patients undergoing primary cementless THA, using a posterior approach, who are treated with rivaroxaban for thromboembolic prophylaxis, short- and long-TXA IV protocols are significantly more effective than placebo in reducing perioperative real <P 0> blood loss </> (RBL), without any <P 0> thromboembolic complications </>. Non-inferiority of a short- versus a long-TXA protocol in reducing perioperative real <P 0> blood loss </> (RBL) was supported in a secondary analysis.