30576544\_PD.txt

Title: A dose-finding randomized Phase II study of oral netupitant in combination with palonosetron .75 mg intravenous for the prevention of chemotherapy-induced <P 0> nausea </> and <P 0> vomiting </> in Japanese patients receiving highly emetogenic chemotherapy.

Publication Type: Journal Article

Journal-Name:Japanese journal of clinical oncology

Journal ID: 0313225

Publication date: 2018/12/24 06:00 [pubmed]

Objective: Netupitant is a novel, selective neurokinin-1 receptor antagonist used for prevention of chemotherapy-induced nausea and vomiting, a distressing side effect of chemotherapy. This double-blind, randomized, Phase II study investigated the dose-response of oral netupitant in Japanese patients receiving highly emetogenic chemotherapy. Methods: Chemotherapy-naive patients were randomized (1:1:1) to a single oral netupitant 30-, 100- or 300-mg dose before chemotherapy initiation. Patients received concomitant palonosetron (0.75 mg intravenously [i.v.] Day 1) and dexamethasone (9.9 mg i.v. Day 1, 8 mg orally Days 2-4). Results: Overall, 402 patients (30 mg: 134; 100 mg: 135; 300 mg: 133) were treated and evaluable for efficacy and safety. The primary endpoint of overall (0-120 h after chemotherapy administration) <P 0> complete response (CR) </> rate (no emesis, no rescue medication) was 64.2%, 60.0% and 54.9% in the 30-, 100- and 300-mg arms, respectively, without statistical significance for dose-response. The safety profile of netupitant was comparable in the three arms. The plasma concentrations of <P 0>(S1) netupitant <P 0> and {its} metabolites </> increased with the dose increase from 30 mg to 300 mg. Conclusions: No dose-response relationship of netupitant in terms of overall <P 0> complete response </> rate was observed in this study. Netupitant was well <P 32> tolerated </> at all doses without clinically harmful safety signals observed. Clinical trial registration: JapicCTI-142 483.

30576772\_PD.txt

Title: Study on the safety of Polygala tenuifolia Willdenow root extract powder (BT-11) in young person aged from 9 to 19 years old.

Publication Type: Randomized Controlled Trial

Journal-Name:Journal of ethnopharmacology

Journal ID: 7903310

Publication date: 2018/12/16 00:00 [accepted]

ETHNOPHARMACOLOGICAL RELEVANCE: Polygala tenuifolia Willdenow root extract (BT-11) has beneficial effects on central nervous system disorders in human. The safety of BT-11 should be elucidated in younger person further. AIM OF THE STUDY: To evaluate the safety of BT-11 in human aged from 9 to 19 years old. MATERIAL AND METHODS: The safety was evaluated in randomly assigned subjects who received the test products (61 subjects in BT-11 300mg daily or 60 subjects in matching placebo) for 12 weeks. <P 38> Adverse reactions </> were analyzed by the incidence rate, type, and severity. The clinical examination included <P 0> hematology </> and <P 0> blood chemistry </> tests, <P 0> urinalysis </>, <P 0> vital signs </>, <P 0> body weight </>, and <P 0> electrocardiogram (ECG) </>. RESULTS: Eleven <P 38> adverse reactions </> were observed in ten subjects receiving BT-11 while seven <P 38> adverse reactions </> in six subjects receiving placebo. There were no statistical differences in the incidence of <P 38> adverse reactions </> between the two groups. <P 38> Serious adverse reactions </> such as <P 0> acute appendicitis </> and <P 0> acute viral gastroenteritis </> were observed in the BT-11 group4 and the placebo group, respectively. However, it was confirmed that they were not associated with the test product. All other <P 38> adverse reactions </> observed during the test period were resolved completely without special treatment. No statistical difference was also observed in safety laboratory tests, <P 0> vital signs </>, and <P 0> electrocardiogram (ECG) </> between two groups. CONCLUSIONS: This study demonstrates the safety of BT-11 in the adolescent by showing no apparent <P 38> adverse reactions </> related to it.

30577513\_PD.txt

Title: beta-Eudesmol, an Oxygenized Sesquiterpene, Reduces the Increase in Saliva <P 0> 3-Methoxy-4-Hydroxyphenylglycol </> After the "Trier Social Stress Test" in Healthy Humans: A Randomized, Double-Blind, Placebo-Controlled Cross-Over Study.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2018/12/19 00:00 [accepted]

Hops, the immature inflorescences of the female hop plant (Humulus lupulus L.) are one of the main components of beer and provides flavor and bitterness. beta-Eudesmol, an oxygenated sesquiterpene, is reported to accumulate in a particular hop cultivar. Recently, we revealed that beta-Eudesmol ingestion affected autonomic nerve activity in an animal model. The effect on humans has not been elucidated, therefore, we investigated the effects of beta-Eudesmol on reducing objective and subjective markers related to <P 0> sympathetic nerve activity </> after the application of mental stress in healthy participants. Fifty participants (male and female aged 20 to 50 years) were randomly assigned to two groups. Five minutes before taking the Trier Social Stress Test (TSST) as a mental stressor, participants in each group ingested a beverage containing beta-Eudesmol, the active beverage, or a placebo beverage that did not contain beta-Eudesmol. Saliva <P 0> 3-methoxy-4-hydroxyphenylglycol (MHPG) </>, a major product of noradrenaline breakdown and a representative marker of <P 0> sympathetic nerve activity </>, was significantly lower just after the TSST in the active group compared with the placebo group. Saliva <P 0> cortisol </>, a marker of the <P 0> endocrine stress response </> system, was not significantly different between the two groups. No <P 38> adverse events </> related to test beverage ingestion were observed. This is the first experimental evidence of beta-Eudesmol effect for mental stress in human.

30577611\_PD.txt

Title: The Effect of Whey and Soy Protein Isolates on <P 29> Cognitive Function </> in Older Australians with Low Vitamin B12: A Randomised Controlled Crossover Trial.

Publication Type: Randomized Controlled Trial

Journal-Name:Nutrients

Journal ID: 101521595

Publication date: 2018/12/17 00:00 [accepted]

Whey protein isolate (WPI) is high in vitamin B12 and folate. These and other related markers (holotranscobalamin, methylmalonic acid and homocysteine) have been linked with cognitive health. This study explored the efficacy of WPI for improving <P 29> cognitive function </> via delivery of vitamin B12. Moderately vitamin B12-deficient participants aged between 45 and 75 years (n = 56) were recruited into this randomised controlled crossover trial. Participants (55% female) consumed 50 g whey (WPI; active) or soy protein isolate (SPI; control) for eight weeks. Following a 16-week washout phase, they consumed the alternative supplement. Consumption of WPI significantly improved <P 0> active B12 </> and <P 0> folate </> status but did not result in direct improvements in <P 29> cognitive function </>. However, there was evidence of improvement in <P 25> reaction time </> (p = 0.02) and <P 29> reasoning speed </> (p = 0.04) in the SPI condition for females. Additional analyses showed that changes in <P 0> active B12 </>, <P 0> HcY </> and <P 0> folate </> measures during WPI treatment correlated with improvements in <P 29> cognitive function </> (all p < 0.05). Results indicate that WPI itself did not result in improved <P 29> cognitive function </> but some evidence of benefit of SPI for females was found. However, consistent with previous research, we present further evidence of a role for <P 0> active B12 </>, <P 0> HcY </> and <P 0> folate </> in supporting <P 29> cognitive </> improvement in adults with low B vitamin status.

30577730\_PD.txt

Title: Alcohol pictorial health warning labels: the impact of self-affirmation and health warning severity.

Publication Type: Randomized Controlled Trial

Journal-Name:BMC public health

Journal ID: 100968562

Publication date: 2018/12/23 06:00 [entrez]

BACKGROUND: We examined whether enhancing self-affirmation among a population of drinkers, prior to viewing threatening alcohol pictorial health warning labels, would reduce <P 25> defensive reactions </> and promote <P 25> reactions </> related to behaviour change. We also examined how health warning severity influences these <P 25> reactions </> and whether there is an interaction between self-affirmation and severity. METHODS: In this experimental human laboratory study, participants (n = 128) were randomised to a self-affirmation or control group. After the self-affirmation manipulation was administered, we tracked participants' <P 0> eye movements </> while they viewed images of six moderately-severe and six highly-severe pictorial health warning labels presented on large beer cans. Self-reported <P 25> responses </> to the pictorial health warning labels were then measured, including <P 25> avoidance </>, <P 25> reactance </>, effectiveness, <P 28> susceptibility </> and <P 28> motivation </> to drink less. Finally, participants reported their <P 28> self-efficacy </> to drink less and their <P 0> alcohol use </>. RESULTS: There was no clear evidence that enhancing self-affirmation influenced any outcome. In comparison to moderately-severe health warnings, highly-severe health warnings increased <P 25> avoidance </> and <P 25> reactance </> and were perceived as more effective and increased <P 28> motivation </> to drink less. CONCLUSIONS: These findings call into question the validity of the self-affirmation manipulation, which is purported to reduce <P 25> defensive reactions </> to threatening warnings. We discuss possible explanations for this null effect, including the impact of participants' low perceived susceptibility to the risks shown on these pictorial health warning labels. Our finding that highly-severe health warnings increase <P 25> avoidance </> and <P 25> reactance </> but are also perceived as being more effective and more likely to <P 28> motivate </> people to drink less will inform future health warning design and have implications for health warning label theory.

30579372\_PD.txt

Title: Precooling, Exertional Heatstroke Risk Factors, and Postexercise Cooling Rates.

Publication Type: Randomized Controlled Trial

Journal-Name:Aerospace medicine and human performance

Journal ID: 101654770

Publication date: 2019/02/26 06:00 [medline]

BACKGROUND: Precooling (PC) before exercise may help prevent severe hyperthermia and exertional heatstroke (EHS). Before clinicians can advocate PC as an EHS prevention strategy, it must effectively mitigate factors associated with EHS development while not lessening the effectiveness of EHS treatment. Therefore, this study determined if PC affected <P 0> rectal temperature (Trec) </>, <P 0> body heat storage </>, <P 0> heart rate (HR) </>, ratings of <P 0> perceived exertion </> (RPE), <P 0> thermal sensation </>, <P 0> sweat </> rate, and postexercise cold-water immersion (CWI) <P 0> rectal temperature </> cooling rates. METHODS: In this randomized, crossover, counterbalanced study, 12 subjects (6 men, 6 women; age = 22 +/- 2 yr; mass = 73.5 +/- 7.9 kg; height = 171 +/- 7 cm) underwent 15 min of CWI (10.0 +/- 0.03 degrees C) in an environmental chamber (38.6 +/- 0.6 degrees C; 36 +/- 2% humidity). After a 10-min rest, they exercised to a Trec of 39.5 degrees C. Subsequently, they underwent CWI (9.99 +/- 0.03 degrees C) until Trec reached 38 degrees C. On control (CON) days, the same procedures occurred without the 15-min PC intervention. <P 0> Rectal temperature </>, <P 0> heart rate </>, <P 0> thermal sensation </>, and ratings of <P 0> perceived exertion </> were measured at various times before, during, and after exercise. RESULTS: PC lowered <P 0> body heat storage </> and <P 0> rectal temperature </> by 15.7 +/- 15.0 W . m(-2) and 0.42 +/- 0.40 degrees C, respectively, before exercise. Subjects exercised significantly longer (PC = 66.7 +/- 16.3 min, CON = 45.7 +/- 9.5 min) and at lower <P 0> rectal temperature </> (approximately 0.5 +/- 0.5 degrees C) and <P 0> heart rate </> (approximately 10 +/- 7 bpm) following PC. PC significantly lowered <P 0> sweat </> rate (PC = 1.02 +/- 0.31 L . h(-1), CON = 1.22 +/- 0.39 L . h(-1)), but did not affect ratings of <P 0> perceived exertion </> or CWI <P 0> cooling </> rates (PC = 0.18 +/- 0.14 degrees C . min(-1); CON = 0.19 +/- 0.05 degrees C . min(-1)). <P 0> Thermal sensation </> significantly differed between conditions only at pre-exercise (PC = 3 +/- 1, CON = 5 +/- 0.5).DISCUSSION: PC delayed <P 0> severe hyperthermia </> and mitigated <P 0> dehydration </> without affecting <P 0> thermal perception </> or <P 0> cooling </> rates posthyperthermia. PC may help prevent dangerous hyperthermia in athletes.Wohlfert TM, Miller KC. Precooling, exertional heatstroke risk factors, and postexercise cooling rates. Aerosp Med Hum Perform. 2019; 90(1):12-17.

30579406\_PD.txt

Title: Patient coping and expectations predict <P 0> recovery </> after major orthopaedic trauma.

Publication Type: Multicenter Study

Journal-Name:British journal of anaesthesia

Journal ID: 0372541

Publication date: 2018/07/06 00:00 [accepted]

BACKGROUND: Persistent post-surgical pain and associated disability are common after a traumatic fracture repair. Preliminary evidence suggests that patients' beliefs and perceptions may influence their prognosis. METHODS: We used data from the Fluid Lavage of Open Wounds trial to determine, in 1560 open fracture patients undergoing surgical repair, the association between Somatic PreOccupation and Coping (captured by the SPOC questionnaire) and recovery at 1 yr. RESULTS: Of the 1218 open fracture patients with complete data available for analysis, 813 (66.7%) reported moderate to extreme <P 0> pain </> at 1 yr. The addition of SPOC scores to an adjusted regression model to predict <P 0> persistent pain </> improved the concordance statistic from 0.66 to 0.74, and found the greatest risk was associated with high (>/=74) SPOC scores [odds ratio: 5.63; 99% confidence interval (CI): 3.59-8.84; absolute risk increase 40.6%; 99% CI: 30.8%, 48.6%]. Thirty-eight per cent (484 of 1277) reported moderate to extreme <P 0> pain interference </> at 1 yr. The addition of SPOC scores to an adjusted regression model to predict <P 0> pain interference </> improved the concordance statistic from 0.66 to 0.75, and the greatest risk was associated with high SPOC scores (odds ratio: 6.06; 99% CI: 3.97-9.25; absolute risk increase: 18.3%; 95% CI: 11.7%, 26.7%). In our adjusted multivariable regression models, SPOC scores at 6 weeks post-surgery accounted for 10% of the variation in short form-12 <P 25> physical </> component summary scores and 14% of short form-12 <P 28> mental </> component summary scores at 1 yr. CONCLUSIONS: Amongst patients undergoing surgical repair of open extremity fractures, high SPOC questionnaire scores at 6 weeks post-surgery were predictive of <P 0> persistent pain </>, reduced <P 30> quality of life </>, and <P 0> pain interference </> at 1 yr. CLINICAL TRIAL REGISTRATION: NCT00788398.

*30579416\_PD.txt*

*Title: Performance of Litholyme compared with Sodasorb carbon dioxide absorbents in a standard clinical setting.*

*Publication Type: Letter*

*Journal-Name:British journal of anaesthesia*

*Journal ID: 0372541*

*Publication date: 2018/09/21 00:00 [accepted]*

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30580857\_PD.txt

Title: Remote ischemic preconditioning for prevention of <P 0> contrast induced nephropathy </> -Insights from an Indian study.

Publication Type: Randomized Controlled Trial

Journal-Name:Indian heart journal

Journal ID: 0374675

Publication date: 2017/11/15 00:00 [accepted]

OBJECTIVES: To study if four cycles of remote ischemic preconditioning (RIPC) could offer protection against <P 0> contrast induced nephropathy (CIN) </> and post procedural <P 0> renal dysfunction </> in high risk patients undergoing percutaneous coronary intervention (PCI). METHODS: This was a prospective single blind randomized sham controlled trial where patients undergoing coronary angioplasty with stage III chronic kidney disease were randomized into sham preconditioning and remote ischemic preconditioning. The primary outcome was the reduction in the incidence of <P 0> contrast induced nephropathy (CIN) </>. The secondary outcomes were the maximum improvement in <P 0> eGFR </>, maximum reduction in serum <P 0> creatinine </> and composite of requirement of <P 36> hemodialysis </>, <P 1> death </> and <P 35> rehospitalization for heart failure </> up to 6 weeks after PCI. RESULTS: Eleven out of fifty patients in the study group developed <P 0> contrast induced nephropathy (CIN) </> (22%) compared to eighteen out of the fifty control patients (36%) (p=0.123). There was a statistically significant improvement in the post procedure <P 0> creatinine </> values at 24h (p=0.013), 48h (p=0.015), 2 weeks (p=0.003), 6 weeks (p=0.003) and post procedure <P 0> glomerular filtration rate (eGFR) </> values at 24h (p=0.026), 48h (p=0.044), 2 weeks (p=0.015) and 6 weeks (p=0.011) in study group compared to control group. The secondary outcome composite of requirement of <P 36> hemodialysis </>, <P 1> death </> and <P 35> rehospitalization for heart failure </> was not statistically significant (p: 0.646). CONCLUSION: RIPC does not result in significant reduction of <P 0> contrast induced nephropathy </>. However RIPC helps in the prevention of post procedural worsening in <P 0> eGFR </> and serum <P 0> creatinine </> even up to 6 weeks.

*30581173\_PD.txt*

*Title: Baltimore CONNECT: A Randomized Trial to Build Partnership Between Community Organizations and a Local Health System.*

*Publication Type: Randomized Controlled Trial*

*Journal-Name:Progress in community health partnerships : research, education, and action*

*Journal ID: 101273946*

*Publication date: 2019/03/08 06:00 [medline]*

*BACKGROUND: Community-based organizations (CBOs) are key partners in supporting care, but health systems and CBOs operate in silos. Baltimore Community-based Organizations Neighborhood Network: Enhancing Capacity Together (CONNECT) was a randomized, controlled trial based on the core tenets of the World Health Organization's (WHO) African Partnerships for Patient Safety Community Engagement (ACE) approach. OBJECTIVES: We describe a research protocol and lessons learned from a partnership between Johns Hopkins Health System and 11 CBOs. METHODS: Baltimore CONNECT involved 22 CBOs in East Baltimore randomized to a co-developed intervention bundle versus control. Data were from review of notes and minutes from meetings, and discussions with each CBO on value added by intervention elements and on impact of the project. LESSONS LEARNED: It is feasible to engage and maintain a network of CBOs linked with a local health system. CONCLUSIONS: The WHO ACE approach supported development and sustainment of a network of organizations linking health care and social services across East Baltimore.*