Safety and Efficacy of a Pre-Workout Dietary Supplement with and without Synephrine

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Abstract

Background A number of nutritional strategies have been developed to optimize nutrient delivery prior to exercise. As a result, a number of pre-workout supplements have been developed to increase energy availability, promote vasodilation, and/or positively affect exercise capacity. The purpose of this study was to examine the safety and efficacy of a pre-workout dietary supplement with and without synephrine.

Methods In a double-blind, crossover, randomized and placebo-controlled manner; 25 apparently healthy and recreationally active men and women (21.76±3.00 yr, 15.24±5.26% fat, 25.09±3.03 kg/m^2) had the first blood donation after 10-12 hours fasting, and then after 2 hours of a pre-workout supplement ingestion, participants had the second blood donation. Participants ingested in a randomized and counterbalanced manner a dextrose flavored placebo (P); a pre-workout supplement (PWS) containing 3 g beta alanine, 2 g creatine nitrate, 2 g arginine AKG, 300 mg N-acetyl tyrosine, 270 mg caffeine, 15 mg Mucuna pruriens; or, the PWS with 20 mg synephrine (PWS+S). Participants repeated the experiment after a one week washout period with the alternate supplements in a randomized and counterbalanced manner. Data were analyzed by repeated measure ANOVA and presented as means (95% CI) delta change from baseline.

Results Delta analysis revealed significant differences among groups in mean change in blood urea nitrogen (BUN) (unit conversion to mg/dl by mmol/l x 2.8011): P (-1.51 mg/dl; -2.26, -0.78), PWS (-2.26 mg/dl; -2.99, -1.54), and PWS+S (-0.56 mg/dl; -1.28, 0.14), creatinine (CRE) (unit conversion to mg/dl by μmol/L x 0.0113): P (0.05 mg/dl; 0.01, 0.10), PWS (0.14 mg/dl; 0.09, 0.19), and PWS+S (0.14 mg/dl; 0.09, 0.18). An overall Wilks' Lambda time (p<0.01) and time x group (p<0.01) interactions for BUN, CRE and the ratio of BUN/CRE (BCr), and Greenhouse-Geisser univariate analysis for BUN, CRE and BCr (p<0.01) were found. Wilks' Lambda analysis revealed a significant time effect (p<0.00) of alkaline phosphatase (ALP), aspartate amino transferase (ALT), and alanine amino transferase (AST), and of creatine kinase (CK) and lactate dehydrogenase (LDH), with no time x group interactions (p>0.05). MANOVA Greenhouse-Geisser univariate analysis revealed significant changes over time for ALP, ALT and AST (p<0.01), and CK and LDH (p<0.01). Delta analysis revealed significant differences among groups in mean change in total cholesterol (CHOL): P (0.31 mmol/L; 0.12, 0.50), PWS (-0.16 mmol/L; -0.35, 0.02), and PWS+S (0.31 mmol/L; 0.12, 0.50). An overall Wilks' Lambda time (p<0.01) and time x group (p<0.01) interactions for CHO, HDL-C, LDL-C and triglyceride (TAG), and Greenhouse'Geisser univariate analysis for CHO, HDL-C, and LDL-C (p<0.01) were found. Delta analysis revealed significant differences among groups in mean change in glucose: P (0.60 mmol/L; 0.21, 0.99), PWS (0.77 mmol/L; 0.39, 1.15), and PWS+S (1.29 mmol/L; 0.90, 1.68). A significant time x group interactions (p<0.03) of glucose was found.

Conclusion Ingesting a dietary PWS or PWS+S had minor affects within 3 hours, similar to P, on kidney function, liver enzymes, blood lipid levels, muscle enzymes, and blood sugar levels. These findings are in agreement with other studies testing similar ingredients.

Background

Many individuals seek ergogenic aids to enhance their sports performance. Pre-workout supplements geared to increase workout intensity are one such supplement. Health safety is one of the main concerns of supplement usage. This study examines the potential health concerns of a pre-workout supplement with and without synephrine.

Methods

- 25 apparently healthy and recreationally active men and women (21.76±3.00 yr, 15.24±5.26% fat, 25.09±3.03 kg/m^2) participated in this study
- The first blood donation occurred after 10-12 hours of fasting
- Participants then ingested the pre-workout supplement containing 3 g beta alanine, 2 g creatine nitrate, 2 g arginine AKG, 300 mg N-acetyl tyrosine, 270 mg caffeine, 15 mg Mucuna pruriens with (PWS+S) and without (PWS) 20 mg of synephrine, or a placebo (P) of flavored dextrose
- A variety of test s were conducted including 3 sets of 10 repetitions of both leg press and bench press and a Wingate anaerobic test
- Approximately 2 hours after supplement ingestion a 2nd blood draw was performed
- Blood samples were analyzed on a COBAS c111 for the following:
  - blood urea nitrogen (BUN)
  - creatinine (CRE)
  - alkaline phosphatase (ALP)
  - aspartate amino transferase (ALT)
  - alanine amino transferase (AST)
  - creatine kinase (CK)
  - lactate dehydrogenase (LDH)
  - total cholesterol (CHOL)
  - HDL cholesterol (HDL)
  - LDL cholesterol (LDL)
  - triglyceride (TAG)
  - glucose (GLU)

Statistical Analyses

Data were analyzed by MANOVA, using IBM SPSS for Windows version 22.0 software (Chicago, IL). Data are presented as changes from baseline as mean change; 95% confidence interval

Results

- Wilks' Lambda time (p<0.01) and time x group (p<0.01) interaction for BUN), CRE, and the ratio of BUN/CRE were found
  - Greenhouse-Geisser univariate analysis revealed significant changes over time (p<0.01) and time x group interactions (p<0.05) for BUN and CRE
  - Significant changes between groups PWS and PWS+S were found for BUN
  - Significant changes between group P and groups PWS and PWS+S were found for CRE
- Wilks' Lambda analysis revealed a significant time effect (p<0.01) for ALP, ALT, and AST, with no time x group interactions (p>0.05)
  - Greenhouse-Geisser univariate analysis revealed significant changes over time (p<.01) for ALP, ALT and AST
- Wilks' Lambda analysis revealed a significant time effect (p<0.01) for CK and LDH, with no time x group interactions (p>0.05)
  - Greenhouse-Geisser univariate analysis revealed significant changes over time (p<.01)for CK and LDH
- Wilks' Lambda time (p<0.01) and time x group (p<0.01) interaction for CHOL, HDL, LDL, and TAG were discovered
  - Greenhouse-Geisser univariate analysis revealed significant changes over time (p<.01) for CHOL, HDL, and LDL, with time x group interactions (p<0.05) for CHOL
  - Significant changes between group PWS and groups PWS+S and P were found for CHOL
- Significant time (p<.01) and time x group (p<.05) interactions for GLU were found between the PWS+S and P groups

Conclusions & Applications

- These findings demonstrated PWS and PWS+S induce changes in kidney function, liver enzymes, blood lipid levels, muscle enzymes, and blood sugar levels similar to placebo. Minor changes were noted
- It appears this supplement is safe for human consumption under acute conditions
- Further research is needed to verify safety with chronic usage

Acknowledgements & Disclosures

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