

The Safety of a Pre Workout Supplement in Healthy Individuals: A Twenty Eight Day Evaluation

Matt M. Mosman, Jordan M. Joy, Paul H. Falcone, Roxanne M. Vogel, Chad M. Hughes, Jonathan D. Griffin, Kacey J. Paulin
Michael P. Kim, Jordan M. Moon

ABSTRACT

In recent years, the consumption of multi-ingredient supplements in the pre-exercise time period in order to obtain ergogenic benefits has become increasingly popular. Ingesting pre-workout supplement(s) (PWS) is one approach used by athletes and recreational populations to aid performance and maximize training adaptations. Purported benefits include increases in strength, improved focus, and sustained energy during exercise. While research exists on the ergogenic benefits of PWS, less is known regarding the safety and potential side effects of chronic consumption. **PURPOSE:** The purpose of this study was to examine the safety of consuming a PWS containing caffeine, amino acids, creatine, and beta-alanine over a 28 day period. **METHODS:** 62 young males and females (26.7 ± 4.8 years, 173.3 ± 9.2 cm, 76.8 ± 18.0 kg) participated in this study. Subjects were equally and randomly assigned to consume either 1 (G1; n = 22) or 2 (G2; n = 18) servings daily of a pre-workout supplement or remain un-supplemented (CON; n = 22). Fasting blood samples (white blood cells, red blood cells, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, red cell distribution width, platelets, neutrophils, lymphocytes, monocytes, eosinophils, basophils, absolute neutrophils, absolute lymphocytes, absolute monocytes, absolute eosinophils, absolute basophils, immature granulocytes, absolute immature granulocytes, glucose, blood urea nitrogen (BUN), creatine (Cr), eGFR, BUN:CR ratio, sodium (Na), potassium, chloride, carbon dioxide, calcium, total protein, albumin, globulin, albumin:globulin ratio, bilirubin, alkaline phosphatase, aspartate aminotransferase (AST), alanine aminotransferase (ALT), total cholesterol, triglycerides, high density lipoprotein, and low density lipoprotein) along with resting blood pressure and heart rate were taken before and after the 28 day period. All groups were instructed to maintain and record their normal dietary and exercise habits and keep a supplementation and adverse event log for the duration of the study. **RESULTS:** Repeated measures ANOVA revealed no significant interactions between groups (p < 0.05) for all measures. Means and standard deviations for selected variables representative of heart, liver, and kidney function are presented in Table 1. All dependent variables remained within normal clinical reference ranges. No adverse events were reported in this study.

CONCLUSIONS: Overall, the PWS appears to be safe in both 1 and 2 serving doses consumed daily for up to a 28 day period in healthy males and females. **PRACTICAL APPLICATIONS:** Healthy men and women who use the recommended dosage for this PWS may not experience any detrimental health risks. This study suggests the a PWS supplement containing caffeine, amino acids, creatine, and beta-alanine is safe for chronic supplementation.

INTRODUCTION

An emerging trend in supplementation is the use of pre-workout supplements (PWS) before engaging in physical activity. PWS generally contain multiple ingredients that claim to provide ergogenic benefits. Many athletes believe that supplementation prior to training will result in improved strength, focus, and enhanced training adaptations. Multiple studies exist on the benefits of a consuming a PWS; however, limited research has been conducted on the safety of these products. The effects on blood chemistry, hematology values, resting heart rate (RHR), and blood pressure (BP) remain unclear due to the combination of multiple ingredients and proprietary blends found in various PWS. Consequently, as new multi-ingredient PWS are introduced to the market their safety must be evaluated. Therefore, this investigation will examine the safety of ingesting a PWS containing caffeine, amino acids, creatine, and beta-alanine for 28 days in recreationally-trained males and females.

METHODS

Participants

Sixty two recreationally trained males and females participated in this study. Subjects were required to be apparently healthy and free from disease, have no physical condition that was considered a contraindication to cardiovascular training, and abstain from smoking, alcohol, and anti-inflammatories during the 28 day period. In addition, all subjects were required to engage in physical activity at least 2 days per week. Subjects indicated participation in one or more of the following physical activities: resistance training, running, walking, basketball, soccer, crossfit, and rugby. Prior to testing, the study was approved by the MusclePharm Institutional Review Board for use of human subjects, and all subjects provided written informed consent to participate in the study.

Study Design

All subjects were randomly divided into three groups. Group 1 was instructed to ingest one serving while Group 2 was instructed to consume 2 servings of the PWS every day for 28 days. CON remained un-supplemented for the 28 day period. Subjects were not required to consume the PWS prior to exercise, and Group 2 was permitted to consume one serving twice daily. The PWS (Assault™, MusclePharm Corp., Denver, CO) contained caffeine, amino acids, creatine, and beta-alanine.

Prior to the supplementation period, subjects were instructed to report to a local blood testing facility (Laboratory Corporation of America, Denver, CO, USA) in an 8 hour fasted, euhydrated state and not to exercise the morning of testing. Each subject completed an informed consent, health history, and exercise questionnaire. Resting heart rate and blood pressure was taken using an automated blood pressure cuff. The average of two tests with 2 minutes between tests was recorded and used for analysis. Height and weight was measured using a SECA 703 high capacity column scale. Subjects then provided a baseline blood and urine sample for full safety panels.

After baseline measurements were completed, subjects were provided with the PWS supplement and instructed to record a supplementation and adverse events log for 28 days. They were also instructed to maintain and record their current diet and exercise routine as it had been for at least two months prior to the start of the study. Maintenance of diet was monitored using 3 day food logs for each week. At the conclusion of the 28 day supplementation period, subjects were instructed to return to the blood testing facility in an identical state to baseline testing to provide a post blood and urine sample, height, weight, blood pressure, and heart rate. Supplementation, food, exercise, and adverse event logs were also collected at this time.

Blood Draws/Urinalysis

All blood (taken via venipuncture by a trained phlebotomist) and urine samples were done at a local diagnostic laboratory (Laboratory Corporation of America, Denver, CO, USA). Pre supplementation samples were taken with the subject in an 8 hour fasted, euhydrated state while post samples were taken in an identical state one day after ceasing supplementation and at the same time of day as pre supplementation blood and urine samples. Variables recorded from the blood and urine analysis consisted of white blood cell count (WBC), red blood cell count (RBC), hemoglobin, hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets (percent and absolute), neutrophils (percent and absolute), lymphocytes (percent and absolute), monocytes (percent and absolute), eosinophils (percent and absolute), basophils (percent and absolute), serum glucose, blood urea nitrogen (BUN), creatinine, eGFR, BUN:creatinine, sodium, potassium, chloride, carbon dioxide, calcium, protein, albumin, globulin, albumin:globulin ratio (A/G ratio, bilirubin), alkaline phosphatase, aspartate aminotransferase (AST), alanine aminotransferase (ALT), total cholesterol, triglycerides, high density lipoprotein (HDL), low density lipoprotein (LDL), ammonia, urine specific gravity, pH, and urobilinogen.

Subject Characteristics

	n	Age	Height	Weight
All	62	26.7 ± 4.8 years	173.3 ± 9.2 cm	76.8 ± 18 kg

Supplement Facts



	Amount Per Serving	%DV
Calories	10	
Total Carbohydrates	3 g	1%
Sugars	2 g	
Vitamin C (as Ascorbic Acid)	500 mg	833%
Vitamin E (as Alpha Tocopherol Acetate)	200 IU	667%
Niacin	25 mg	125%
Vitamin B6 (as Pyridoxine Hydrochloride)	15 mg	750%
Vitamin B12 (as Methylcobalamin)	50 mcg	1500%
Calcium (as Silicate, Phosphate and Citrate)	153 mg	15%
Sodium	50 mg	2%
Potassium	40 mg	1%
ATP AMPLIFIER	3,500 mg	†
Carosyn™ Patented Beta-Alanine (2,000 mg), L-Tyrosine, L-Aspartic Acid, Red Beet Extract High in Nitrates, DMG Dimethylglycine HCl		
CELLULAR TRANSPORT & INSULIN ACTIVATOR 2,952 mg	†	
Dextrose, L-Glycine, Ribose, Circulin PFC (Cinnamonum Burmanni) Bark Extract		
ATHLETE PERFORMANCE BLEND 2,000 mg	†	
FEATURING TON-3 NITRATE TECHNOLOGY MATRIX™ Creatine Nitrate, L-Arginine Nitrate, BCAA Nitrate 3:1:2 Ratio (L-Leucine, L-Valine, L-Isoleucine)		
ENERGY & NEURO IGNITER 1,750 mg	†	
Choline Bitartrate, Glucuronolactone, PureEnergy Matrix (Caffeine Anhydrous, Pterostilbene), Hyperzine A		
HYDRATION SYSTEM 1,200 mg	†	
Banane, Coconut Water Powder, L-Glutamine		

†Percent Daily Values are based on a 2,000 calorie diet. †Daily Value not established.

RESULTS

Variable	Treatment	PRE	POST	Reference Interval	p
Systolic Blood Pressure (mmHg)	CON	119.32 ± 13.07	110.55 ± 5.56	90-120	0.08
	G1	119.80 ± 14.04	115.98 ± 13.84		
	G2	119.56 ± 15.75	120.86 ± 12.50		
Diastolic Blood Pressure (mmHg)	CON	75.09 ± 10.20	75.27 ± 8.59	60-80	0.50
	G1	76.34 ± 10.16	76.41 ± 13.40		
	G2	72.19 ± 8.45	75.86 ± 10.94		
Heart Rate (beats/min)	CON	63.07 ± 10.75	65.86 ± 7.47	< 100	0.85
	G1	63.11 ± 11.73	64.55 ± 16.92		
	G2	64.78 ± 11.67	68.22 ± 17.09		
BUN/CR (mg/dL)	CON	17.32 ± 5.02	16.77 ± 5.04	8-16	0.09
	G1	15.05 ± 3.75	16.37 ± 4.46		
	G2	18.59 ± 6.90	17.53 ± 6.88		
Sodium (mmol/L)	CON	137.36 ± 2.74	136.73 ± 2.00	134-144	0.44
	G1	138.37 ± 1.98	138.74 ± 2.64		
	G2	137.18 ± 1.07	138.24 ± 1.60		
Total Protein (g/dL)	CON	6.88 ± 0.40	6.83 ± 0.39	6.0-8.5	0.67
	G1	6.98 ± 0.40	6.88 ± 0.39		
	G2	6.94 ± 0.49	6.95 ± 0.50		
AST (IU/L)	CON	25.86 ± 9.72	26.50 ± 8.91	0-40	0.34
	G1	26.63 ± 11.50	24.37 ± 7.17		
	G2	32.29 ± 9.41	34.18 ± 11.00		
ALT (IU/L)	CON	24.45 ± 8.90	23.91 ± 8.04	0-44	0.22
	G1	27.68 ± 20.60	20.84 ± 7.04		
	G2	32.18 ± 12.07	32.59 ± 13.87		
Total Cholesterol (mg/dL)	CON	156.64 ± 24.23	154.45 ± 23.36	100-189	0.33
	G1	170.26 ± 25.07	162.58 ± 28.17		
	G2	157.53 ± 30.06	158.41 ± 30.04		
Triglycerides (mg/dL)	CON	87.14 ± 43.82	84.18 ± 48.00	0-114	0.40
	G1	86.21 ± 35.61	84.00 ± 40.27		
	G2	94.88 ± 76.29	105.24 ± 61.07		

CONCLUSIONS

The results of the present study support our hypothesis, indicating that supplementation with Assault™ for 28 days did not produce clinically significant changes in safety markers in healthy, recreationally trained males and females. All assessed blood and urine markers, RHR, and BP remained within normal clinical ranges from pre to post testing. Our results agree with previously reported studies that chronic consumption of a PWS containing similar ingredients is safe in similar populations.

PRACTICAL APPLICATIONS

Healthy men and women who use the recommended dosage for this PWS may not experience any detrimental health risks. This study suggests that a PWS containing caffeine, amino acids, creatine, beta-alanine, and B-vitamins is safe for chronic supplementation.

REFERENCES

- Bishop D: Dietary supplements and team-sport performance. Sports medicine 2010, 40, 995-1017.
- Graham, TE. Caffeine and exercise. Metabolism, endurance, and performance. Sports Med. 2001, 31, 785-807.
- Hoffman JR, Kang J, Ratamess NA, Hoffman MW, Tranchina CP, Faigenbaum AD: Examination of a pre-exercise, high energy supplement on exercise performance. Journal of the International Society of Sports Nutrition 2009, 6:2.
- Malek, MH, TJ Housh, JW Coburn, TW Beck, RJ Schmidt, DJ Housh, and GO Johnson. Effects of eight weeks of caffeine supplementation and endurance training on aerobic fitness and body composition. J Strength Cond Res. 2006, 20:4, 751-755.
- Roberts, MD, VJ Dalbo, SE Hassel, JR Stout, and CM Kersick. Efficacy and safety of a popular thermogenic drink after 28 days of ingestion. J IntSoc Sports Nutr. 2008, 5:19.