A MULTI-INGREDIENT PURPORTED SLEEP AND RECOVERY ENHANCING SUPPLEMENT IS APPARENTLY SAFE FOR CHRONIC CONSUMPTION IN HEALTHY MALES AND FEMALES

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Background

The practice of using multiple ingredients in sports supplements to increase the ergogenic effects of a single finished product is becoming more common. In certain cases, these ingredients interact to produce one synergistic effect, such as enhanced recovery following strenuous exercise. However, there may be unintended negative consequences of such interactions.

Purpose

Therefore, the purpose of this investigation was to determine the safety of a multi-ingredient supplement (MIS) intended to aid restful sleep and enhance recovery of fatigued muscles.

Methods

46 recreationally-active adult males and females (23 males, 23 females, 26.9±5.1y, 170.0±12.2cm, 75.7±18.1 kg) participated in this study. Participants were randomly assigned to consume either 1 (G1; n=13) or 2 (G2; n=13) servings daily of a commercially available MIS, or remain unsupplemented (CRL; n=20) for a period of 28 days. All were instructed to maintain their habitual dietary and exercise routines for the duration of the study. Fasting blood samples, as well as resting blood pressure and heart rate, were taken before and after the supplementation period. Blood samples were analyzed for a complete blood count (red blood cells, white blood cells, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, mean corpuscular volume, hematocrit, hemoglobin, red blood cell distribution width, platelets, neutrophils, monocytes, eosinophils, lymphocytes, basophils, and immature granulocytes), comprehensive metabolic panel (serum glucose, blood urea nitrogen, creatinine, estimated glomerular filtration rate, blood urea nitrogen to creatinine ratio, sodium, potassium, chloride, calcium, carbon dioxide, total protein, albumin, globulin, albumin to globulin ratio, bilirubin, alkaline phosphatase, aspartate aminotransferase, and alanine aminotransferase), and lipid panel (total cholesterol, high density lipoprotein, low density lipoprotein, and triglycerides).

- 23 males, 23 females
- 4 weeks supplementation with Iron Dream
  - 1-serving / day (n = 13)
  - 2-serving / day (n = 13)
  - No supplement (n = 20)
- Blood draws (CBC, CMP, Lipid Panel) pre and post supplementation

Supplement Facts
Serving Size: 5.6 g
Servings Per Container: 30

	Amount Per Serving	% DV*
Calories	5	
Total Carbohydrate	1 g	<1%
Vitamin D (as Cholecalciferol)	500 IU	125%
Vitamin B6 (as Pyridoxine Hydrochloride)	10.5 mg	525%
Magnesium (as Magnesium Aspartate)	125 mg	31%
Zinc (as Zinc Aspartate)	30 mg	200%
Copper (as Copper Glycinate)	10 mcg	1%
Boron (as Boron Citrate)	2 mg	**
Arnold's Dream Proprietary Blend	3,555 mg	**

Night Growth Matrix
L-Glycine, Gamma Amino Butyric Acid (GABA), Mucuna Pruriens 20% L-Dopa, 5-HTP (5-Hydroxytryptophan), Horny Goat Weed (Epimedium Sagittatum) Stem and Leaf Extract, N-Acetyl-5-Methoxytryptamine (Melatonin).

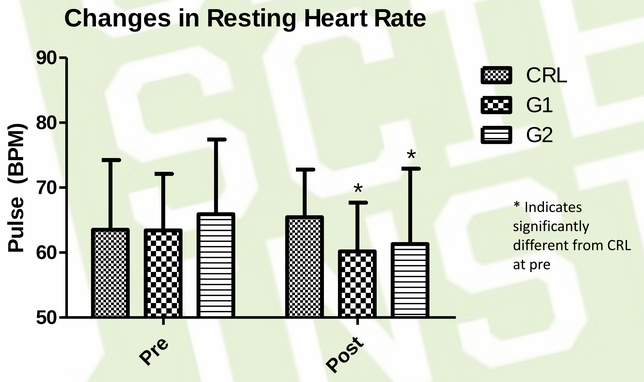
Muscle Recovery Matrix
L-Glutamine, BCAA Nitrate 3:1:2 Blend (L-Leucine, L-Valine, L-Isoleucine), Fenugreek (Trigonella Foenum Greacum) Proprietary Seed Extract Standardized to 50% Saponins.

*Percent Daily Value Based on a 2,000 Calorie Diet
**Daily Value Not Established

Other Ingredients: Natural & Artificial Flavors, Citric Acid, Calcium Silicate, Sucralose, Red Beet Juice Powder (for color), Acesulfame Potassium.

Results

Significant group x time ($p < 0.05$) interactions were observed for heart rate (Figure 1), percent monocytes, serum sodium, and total carbon dioxide (Table 1). No significant interactions ($p > 0.05$) were observed for any other variable (Table 2). All variables with a significant interaction maintained their normality, or non-normality, from pre to post. Two individuals, both from the CRL group, exceeded the minimum difference necessary to be considered to be a real change and also were outside the clinical reference range for sodium. Wherein, one subject decreased from within range to below the minimum accepted clinical value, and one increased from below to within the accepted range. Two individuals, one from CRL and one from G1, exceeded the minimum difference necessary to be considered to be a real change and were also outside the clinical reference range for carbon dioxide. Both individuals decreased from within to below the clinically accepted range. No individuals were observed to have left the accepted range for HR, and a defined range for percent monocytes has not been defined.



Variable	Treatment	PRE	POST	Delta	Reference Interval
Heart Rate (bpm)	CRL	63.5±10.8	65.5±7.3	2.0±6.3	< 100
	G1	63.4±8.7	60.2±7.5*	-3.2±4.5	
	G2	65.9±11.5	61.3±11.6*	-4.6±7.7	
Monocytes (%)	CRL	9.3±2.1	8.3±1.8	-0.95±1.6	4 - 12
	G1	8.5±1.4	9.3±2.0*	0.85±1.1	
	G2	9.5±2.5	9.1±2.5	-0.38±1.8	
Serum Sodium (mmol/L)	CRL	136.9±2.0	136.5±2.1	-0.35±2.4	134 - 144
	G1	139.3±1.8	139.8±1.2*	0.46±1.4	
	G2	140.7±2.1	140.1±2.1*	-0.62±2.2	
Carbon Dioxide (mmol/L)	CRL	22.4±1.6	21.0±1.9	-1.4±1.6	19 - 28
	G1	22.7±1.2	23.1±1.8*	0.38±2.3	
	G2	23.6±2.1	23.2±2.3*	-0.38±1.7	

Table 1. Variables with a significant group x time interaction. * indicates significantly different from CRL.

Variable	Treatment	PRE	POST	Delta	Reference Interval
Serum Glucose (mg/dL)	CRL	81.1±6.4	80.9±11.4	-0.3±10.1	65 - 99
	G1	87.7±5.6	87.3±4.2	-0.4±5.0	
	G2	83.6±4.9	87.9±9.2	4.3±9.5	
BUN (mg/dL)	CRL	17.9±5.6	17.5±4.9	-0.4±3.3	6 - 20
	G1	15.8±2.7	15.5±3.1	-0.4±2.0	
	G2	18.8±5.8	19.4±6.1	0.5±5.5	
Serum Creatinine (mg/dL)	CRL	1.0±0.2	1.0±0.2	0.0±0.1	0.76 - 1.27
	G1	1.0±0.2	1.0±0.2	0.0±0.1	
	G2	1.0±0.2	1.1±0.2	0.0±0.1	
eGFR (mL/min/1.73)	CRL	93.5±13.8	92.9±15.0	-0.6±8.1	>59
	G1	94.5±11.1	93.7±11.2	-0.8±9.4	
	G2	90.0±15.1	88.7±19.7	-1.3±9.8	
BUN/Creatinine Ratio	CRL	18.9±6.3	18.6±5.3	-0.6±9.4	8 - 19
	G1	15.8±2.1	15.5±2.2	-0.9±10.6	
	G2	18.2±4.8	18.3±4.2	-1.4±11.3	
Serum Potassium (mmol/L)	CRL	4.1±0.3	4.1±0.2	0.0±0.3	3.5 - 5.2
	G1	4.5±0.3	4.5±0.3	0.0±0.2	
	G2	4.4±0.3	4.3±0.4	-0.1±0.3	
Serum Chloride (mmol/L)	CRL	101.7±2.1	102.1±2.0	0.4±2.2	97 - 108
	G1	102.6±1.9	102.5±1.3	-0.1±1.8	
	G2	102.5±1.6	101.8±1.9	-0.7±1.2	
Serum Calcium (mg/dL)	CRL	9.3±0.3	9.2±0.3	0.0±0.3	8.7 - 10.2
	G1	9.4±0.2	9.3±0.3	-0.1±0.2	
	G2	9.5±0.3	9.5±0.3	0.0±0.3	
Serum Protein (g/dL)	CRL	7.0±0.3	6.9±0.3	-0.1±0.3	6.0 - 8.5
	G1	6.9±0.3	6.7±0.3	-0.3±0.2	
	G2	6.9±0.2	6.8±0.4	-0.1±0.3	
Serum Albumin (g/dL)	CRL	4.4±0.2	4.4±0.3	0.0±0.2	3.5 - 5.5
	G1	4.4±0.2	4.4±0.3	0.0±0.2	
	G2	4.6±0.2	4.6±0.3	0.0±0.3	
Globulin (g/dL)	CRL	2.6±0.4	2.5±0.4	-0.1±0.2	1.5 - 4.5
	G1	2.5±0.2	2.2±0.2	-0.3±0.1	
	G2	2.3±0.2	2.2±0.4	-0.1±0.3	
Albumin:Globulin Ratio	CRL	1.8±0.3	1.8±0.3	0.1±0.3	1.1 - 2.5
	G1	1.8±0.2	2.0±0.2	0.2±0.2	
	G2	2.1±0.3	2.2±0.4	0.1±0.5	
Bilirubin (mg/dl)	CRL	0.6±0.2	0.5±0.2	0.0±0.2	0.0 - 1.2
	G1	0.2±0.2	0.5±0.2	-0.1±0.3	
	G2	0.1±0.5	0.5±0.4	0.0±0.3	
Alkaline Phosphatase (IU/L)	CRL	60.9±20.8	61.6±21.6	0.7±4.2	39 - 117
	G1	65.2±20.9	65.7±22.0	0.5±6.7	
	G2	73.5±20.2	76.6±28.6	3.1±10.1	
AST (IU/L)	CRL	27.3±9.7	26.2±7.2	-1.2±6.1	0 - 40
	G1	31.3±17.7	23.5±7.2	-7.8±16.5	
	G2	30.5±19.8	26.5±8.2	-4.1±16.7	
ALT (IU/L)	CRL	24.1±8.6	23.0±6.3	-1.2±5.1	0 - 44
	G1	33.1±23.2	24.4±11.9	-8.7±17.7	
	G2	28.6±9.5	28.4±15.7	-0.2±12.1	
Total Cholesterol (mg/dL)	CRL	158.9±26.7	160.0±22.0	1.1±15.5	100 - 199
	G1	156.8±27.5	160.2±22.9	3.4±18.8	
	G2	170.8±29.1	167.1±23.7	-3.8±19.0	
Triglycerides (mg/dL)	CRL	77.7±27.7	84.9±49.6	7.2±27.9	0 - 149
	G1	81.2±40.4	96.0±42.2	14.8±15.0	
	G2	90.8±51.3	105.4±51.5	14.5±40.9	
High Density Lipoprotein (mg/dL)	CRL	61.4±14.4	63.1±15.2	1.7±5.6	>39
	G1	49.8±13.6	50.4±12.5	0.6±6.0	
	G2	49.9±12.4	48.2±12.8	-1.7±5.1	
Low Density Lipoprotein (mg/dL)	CRL	80.9±21.5	80.0±13.4	-0.9±16.6	0 - 99
	G1	90.8±20.9	90.7±18.4	-0.2±14.8	
	G2	102.8±28.3	99.3±22.7	-3.5±17.0	
Systolic BP (mm Hg)	CRL	118.4±10.6	120.8±11.9	2.4±6.2	90 - 120
	G1	116.7±10.8	118.7±14.0	2.0±6.4	
	G2	119.7±13.6	120.3±10.6	0.7±9.1	
Diastolic BP (mm Hg)	CRL	73.1±9.0	72.9±8.3	-0.2±6.6	60 - 80
	G1	73.1±6.5	72.6±6.9	-0.5±5.4	
	G2	74.2±8.4	76.0±9.2	1.8±8.6	
WBC (x10E3/uL)	CRL	6.0±1.8	5.7±1.5	-0.3±0.9	3.4 - 10.8
	G1	5.7±1.2	5.5±1.1	-0.2±1.0	
	G2	6.1±1.6	6.1±1.7	0.0±0.8	
RBC (x10E6/uL)	CRL	4.9±0.3	4.9±0.4	0.0±0.1	4.14 - 5.80
	G1	5.2±0.4	5.2±0.4	0.0±0.2	
	G2	5.2±0.5	5.1±0.5	0.0±0.2	
Hemoglobin (g/dL)	CRL	15.3±1.1	15.2±1.3	-0.1±0.5	12.6 - 17.7
	G1	15.6±1.3	15.4±1.3	-0.2±0.6	
	G2	15.7±1.3	15.6±1.5	-0.1±0.5	
Hematocrit (%)	CRL	45.1±2.8	44.6±3.2	-0.5±1.2	37.5 - 51.0
	G1	45.4±3.0	45.7±3.0	0.2±2.0	
	G2	45.8±3.4	45.7±3.9	-0.1±2.1	
MCV (fL)	CRL	91.9±2.4	91.3±2.7	-0.6±2.0	79 - 97
	G1	87.8±3.4	88.7±3.8	0.9±2.6	
	G2	89.2±4.0	89.6±3.8	0.5±1.7	
MCH (pg)	CRL	30.7±2.0	30.5±2.2	-0.2±0.5	26.6 - 33.0
	G1	30.1±1.2	29.8±1.2	-0.2±0.5	
	G2	30.5±1.4	30.6±1.5	0.1±0.3	
MCHC (g/dL)	CRL	33.9±0.7	34.0±1.0	0.1±0.8	31.5 - 35.7
	G1	34.2±1.0	33.6±0.9	-0.6±0.9	
	G2	34.3±0.5	34.1±0.9	-0.1±0.7	
RDW (%)	CRL	13.3±0.6	13.3±0.5	0.0±0.3	12.3 - 15.4
	G1	13.5±0.9	13.5±0.8	0.0±0.5	
	G2	13.4±0.6	13.3±0.6	-0.1±0.4	
Platelets (x10E3/uL)	CRL	272.0±48.4	257.9±34.6	-14.1±27.0	155 - 379
	G1	251.5±35.7	234.5±35.6	-17.0±14.6	
	G2	256.8±56.1	240.7±50.5	-16.1±22.2	
Neutrophils (%)	CRL	52.8±8.2	51.8±10.1	-1.0±6.2	40 - 74
	G1	51.8±7.4	47.9±8.0	-3.8±6.4	
	G2	51.8±8.3	52.2±9.3	0.4±4.5	
Lymphs (%)	CRL	34.7±7.3	36.5±9.2	1.8±6.0	14 - 46
	G1	36.5±7.1	38.7±6.1	2.2±6.0	
	G2	36.2±6.1	36.4±7.0	0.2±3.8	
Eos (%)	CRL	2.7±1.6	2.9±1.8	0.3±0.9	0 - 5
	G1	2.8±1.8	3.5±2.3	0.7±0.9	
	G2	1.9±1.6	1.8±1.3	-0.1±0.8	
Basos (%)	CRL	0.6±0.8	0.5±0.6	-0.1±0.6	0 - 3
	G1	0.5±0.5	0.5±0.5	0.1±0.5	
	G2	0.6±0.7	0.5±0.7	-0.1±0.3	
Neutrophils (Absolute) (x10E3/uL)	CRL	3.2±1.3	3.0±1.2	-0.2±0.7	1.4 - 7.0
	G1	3.0±1.1	2.7±0.9	-0.4±0.8	
	G2	3.2±1.2	3.2±1.1	0.0±0.5	
Lymphs (Absolute) (x10E3/uL)	CRL	2.1±0.6	2.0±0.6	0.0±0.3	0.7 - 3.1
	G1	2.0±0.3	2.1±0.4	0.0±0.3	
	G2	2.1±0.5	2.2±0.6	0.0±0.3	
Monocytes (Absolute) (x10E3/uL)	CRL	0.6±0.1	0.5±0.1	-0.1±0.1	0.1 - 0.9
	G1	0.5±0.1	0.5±0.1	0.0±0.1	
	G2	0.6±0.2	0.5±0.2	0.0±0.1	
Eos (Absolute) (x10E3/uL)	CRL	0.2±0.1	0.2±0.1	0.0±0.1	0.0 - 0.4
	G1	0.2±0.1	0.2±0.1	0.0±0.1	
	G2	0.1±0.1	0.1±0.1	0.0±0.0	
Baso (Absolute) (x10E3/uL)	CRL	0.0±0.1	0.0±0.0	0.0±0.0	0.0 - 0.2
	G1	0.0±0.0	0.0±0.0	0.0±0.0	
	G2	0.0±0.0	0.0±0.0	0.0±0.0	

Table 2. All variables without a significant interaction.

Conclusions

Resting heart rate decreased in both G1 and G2 relative to control, and no variables deviated from the accepted physiological reference range. Thus, 28 days daily supplementation with the MIS is apparently safe for both recreationally-active males and females in a dose up to 2 servings.

Practical Applications

The MIS can be used by athletes and recreationally-active individuals for the possibility that the MIS will aid recovery and sleep without the fear of adverse health events. It is also a possibility that the MIS may have therapeutic potential in terms of resting heart rate, and further research is warranted.

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Acknowledgements

This study was supported by MusclePharm Corp.