The Effects of a Proprietary Blend of Natural Enzymes on Cardiovascular Health:

An Open-Label Study

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Introduction

In the clinic, a series of standard blood tests, evaluations and procedures are typically used to assess risk and diagnosis of cardiovascular disease (CVD). While the above factors provide a standardized assessment of CVD risk, recent research has sparked significant scientific interest in a variety of biomarkers of CVD risk. Markers of coagulation in the blood describe the thrombotic state of an individual, which is characterized as the capacity for blood clot formation that lead to obstruction of blood flow. Blood clotting occurs as a cascade of enzymatic reactions, ultimately resulting in the conversion of prothrombin to thrombin. Activated thrombin, in turn, converts fibrinogen to fibrin, which creates a mesh-like material that stabilizes platelet aggregation in the clot. In healthy conditions, blood clot formation is induced only upon injury of the blood vessels, which may occur due to infection or trauma. Because blood clots can cause heart attacks and strokes, coagulation is tightly regulated to inhibit excessive or unnecessary clot formation. If the balance between fibrin deposition and removal is shifted in favor of overproduction, it can lead to the formation of dangerous and unnecessary blood clots in the body.

Systemic enzymes have been shown to benefit cardiovascular health by improving blood composition and blood vessel function and further support healthy glucose tolerance and lipid levels. The aim of this study was to demonstrate the effect of a proprietary blend of systemic enzymes including serrapeptase, nattokinase, protease, lipase, bromelain, papain, rutin and amla, on an array of cardiovascular function markers.

Study Participants

Healthy overweight (BMI ≥ 27 and ≤ 30) and obese (BMI ≥ 30 and ≤ 35) volunteers between the age of 18 and 75 years who displayed elevated inflammation (HS-CRP ≥ 2.5 mg/L) and impaired glucose tolerance (Peak OGTT: ≥140 and ≤199) were enrolled in this study. Subjects with a history of congestive heart failure of any classification, unstable angina, or acute coronary syndrome, were excluded from the study.

Clinical Trial Design

This was a 12-week open-label study. The investigational product for this study was Neprinol (Arthur Andrew Medical, Arizona, USA). It consists of a proprietary blend of systemic enzymes, serrapeptase, nattokinase, protease, lipase, bromelain, papain, rutin and amla, as well as cofactors like coenzyme Q10, and magnesium.

Eligible subjects consumed three capsules of the study product, 3 times daily for 12 weeks. Blood was drawn in the clinic at week 0, 6, and 12 and was assessed for markers of coagulation, homocysteine, HS-CRP, lipid profile and OGTT results were recorded for glucose and insulin. At these time-points, vessel function was clinically assessed using an EndoPAT test. Safety was assessed through CBC, CMP, and adverse event analysis.

Results and Discussion

One-hundred sixty three subjects were screened and 14 were enrolled in the study, and a total of 10 subjects completed the study. Platelet Count demonstrated a statistically significant decrease from baseline (262.30 thou/mm3) to Week 12 (207.80 thou/mm3). Systolic Blood Viscosity also showed statistically significant decreases from baseline (47.04 mP) to Week 6 (39.17 mP) and Week 12 (39.48 mP) (16.75%, 16.08%; p=0.039, p=0.034, respectively). Diastolic Blood Viscosity demonstrated statistically significant decreases from baseline (137.64 mP) to Week 6 (110.50 mP) and Week 12 (112.40 mP) (19.72%, 18.34%; p=0.027, p=0.038, respectively).

EndoPAT analysis demonstrated non-significant but favorable changes in Reactive Hyperemia Index (RHI) and Augmentation Index (AI). RHI demonstrated increases of 9.61% and 11.72% at Week 6 and Week 12, respectively, while AI showed a 23.94% reduction at Week 6. Homocysteine demonstrated a statistically significant reduction from baseline (9.38 µmol/L) to Week 6 (8.56 µmol/L) (8.47%, p=0.047).OGTT for glucose demonstrated a significant decrease from baseline to Week 12 at 30 Minutes (14.27%, p=0.021) and a significant increase from baseline to Week 12 (25.04%, p=0.040) at 120 Minutes.

Conclusion

The proprietary blend of natural enzymes (Neprinol) effectively improves systolic and diastolic blood viscosity, circulatory function, and blood sugar levels in healthy overweight or obese individuals with slightly elevated levels of inflammation and impaired glucose tolerance. These results indicate that the study product may improve overall cardiovascular function and health in this non-diseased population.

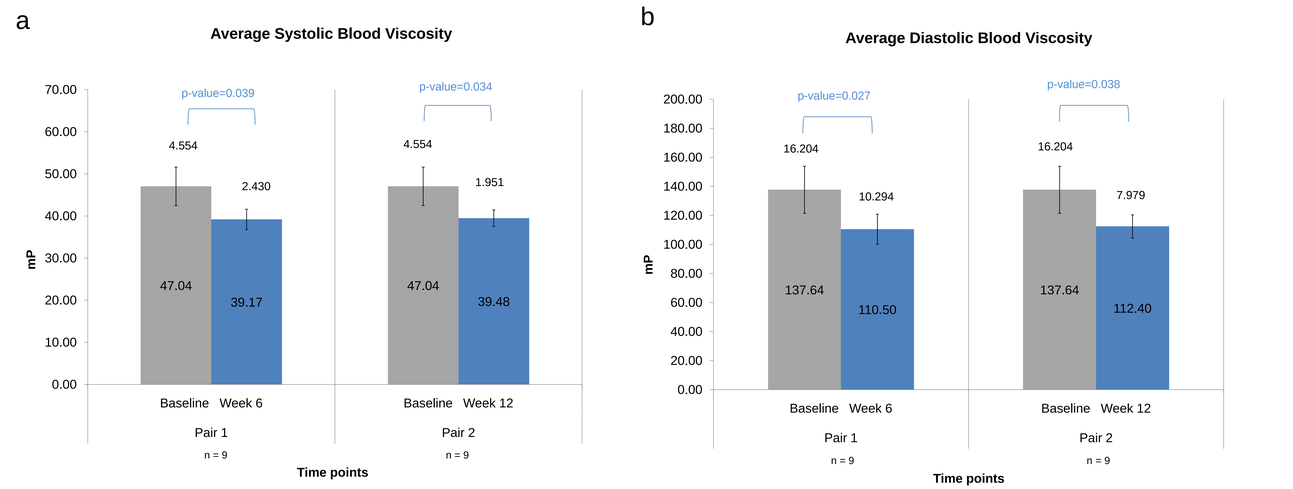

Figure 1. Comparison from baseline to Week 6 and Week 12 in Average Systolic (a) and Diastolic (b) Blood Viscosity. Statistically ssignificant decreases in Average Systolic Blood Viscosity were observed from baseline at all time points (p≤0.05).

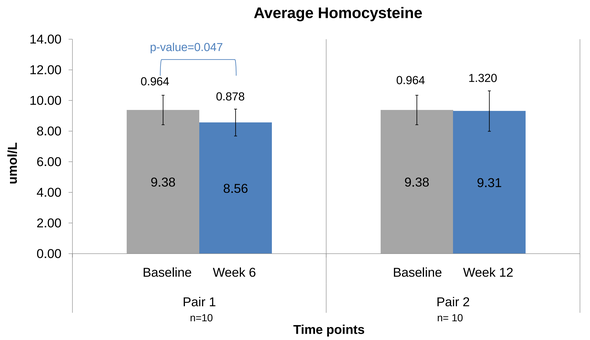

Figure 2. Comparison from baseline to Week 6 and Week 12 in Homocysteine. A statistically significant reduction in Homocysteine was observed from baseline to Week 6 (p≤0.05).

Table 1. Comparison from baseline to Week 6 and Week 12 in RHI and AI. RHI demonstrated non-significant increases at Week 6 and Week 12 while AI showed a non-significant reduction at Week 6.

REACTIVE HYPEREMIA INDEX	Mean	Std. Deviation	Std. Error Mean	Sig.	Percent Change (Other timepoint versus Baseline)
Baseline	1.66	0.397	0.126	0.405	9.61%
Week 6	1.81	0.445	0.141		
Baseline	1.66	0.397	0.126	0.271	11.72%
Week 12	1.85	0.384	0.121		
AUGMENTATION INDEX	**Mean**	**Std. Deviation**	**Std. Error Mean**	**Sig.**	**Percent Change (Other timepoint versus Baseline)**
Baseline	8.02	18.876	5.969	0.568	-23.94%
Week 6	6.10	23.406	7.402		
Baseline	8.02	18.876	5.969	0.722	18.19%
Week 12	9.48	18.841	5.958		

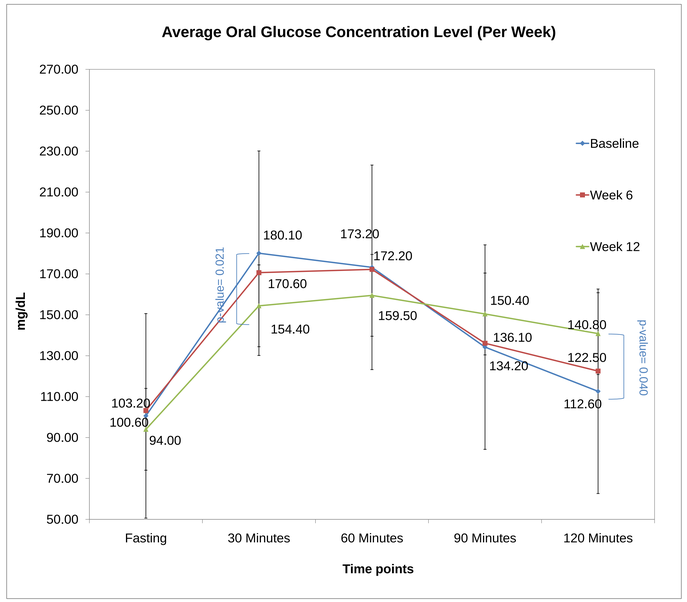

Figure 3. Comparison from baseline to Week 6 and Week 12 in Average Oral Glucose Concentration Level (Per Week). A statistically significant reduction from baseline to Week 12 at 30 Minutes and a significant increase from baseline to Week 12 at 120 Minutes (p≤0.05) were demonstrated.