

An Open-Label, Single-Arm, Pilot Study to Evaluate the Effect of a Proprietary Rhamnan Sulfate (RS) Containing Dietary Supplement on Blood Pressure among Hypertensive Individuals

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Introduction

Almost one in two US adults have hypertension, of which 74% is uncontrolled.¹ Improvement of hypertension is therefore a primary objective in cardiovascular care. A novel approach to hypertension involves focus on the endothelial glycocalyx (EGX). This negatively charged network of proteoglycans, glycoproteins and glycolipids covers the luminal side of the endothelium throughout the vascular system.² The many physiological roles of the EGX include enabling the endothelial production of nitric oxide (NO) production, through triggering of the eNOS enzyme by shear stress of blood flow.³ NO is an essential vasodilator ensuring maintenance of normal blood pressure. The EGX is a fragile structure susceptible to degradation in response to hyperglycemia, inflammation, oxidation, and a variety of other conditions.

A promising approach to improving hypertension is therefore to regenerate and protect the EGX. Several compounds have been studied for EGX regeneration, including natural marine-sourced compounds. One such compound is rhamnan sulfate (RS) from the green seaweed *Monostroma nitidum*, which has been shown to provide a number of potential benefits to cardiovascular function.⁴⁻⁸

This study was commissioned to evaluate the effect of a dietary supplement, containing RS from *Monostroma nitidum* in a proprietary extract: MontiumRS™. The study's primary endpoint was change of systolic blood pressure (SBD) and diastolic blood pressure (DBP).

Methods

Population: Participants (n=10) included males and females aged 16 to 85 years with SBP 140 mm Hg or higher or with DBP 90 mm Hg or higher. Patients with a history of myocardial infarction or stroke within the previous 5 years were excluded.

Intervention: Participants ingested 1 capsule twice per day of Arterosil HP®, a proprietary dietary supplement*, for 3 months. Patients' medications, supplements, exercise, weight-loss or nutrition programs were maintained with no changes for the duration of the study.

Measurements: Participants made 4 visits to the research location: at baseline, after one month, after two months, and after three months. The following measurements were made at baseline, at the end of 2 months, and at the end of three months:

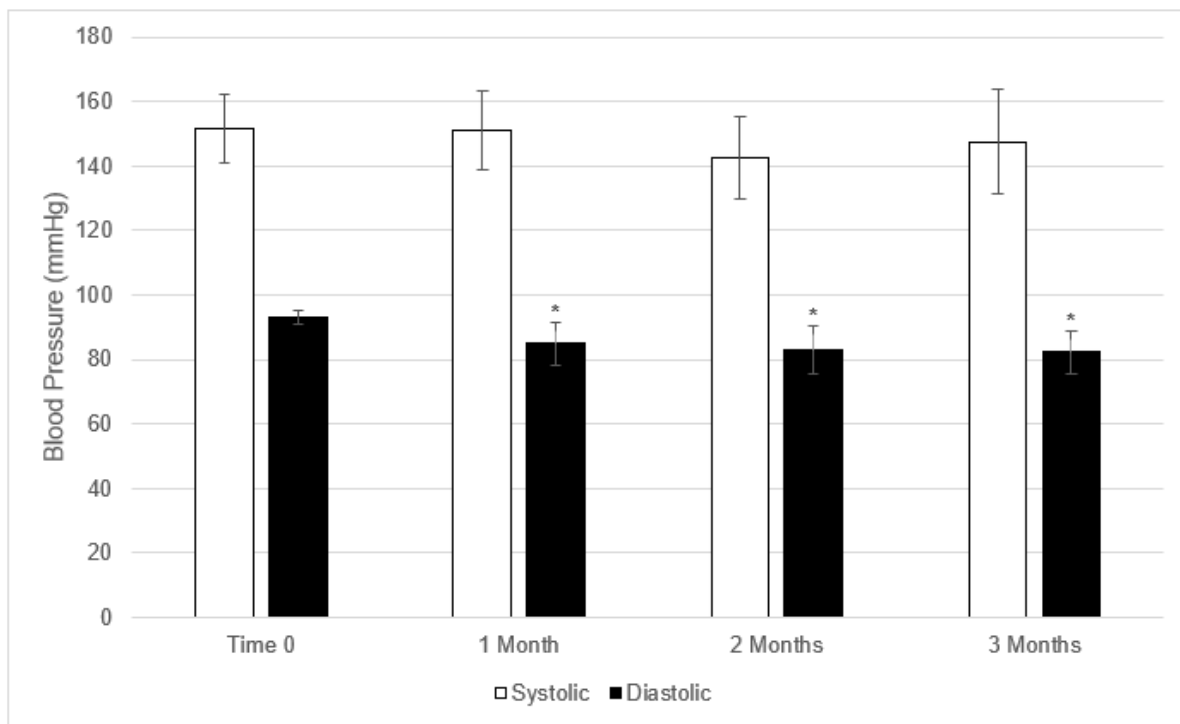
- Blood pressure in the left arm, seated with HR using American Heart Association blood pressure measurement criteria
- Body weight

Results

Systolic blood pressure decreased by 0.5 points at 1 month ($p < 0.8902$), 8.9 points at 2 months ($p < 0.0952$), and 4.0 points at 3 months ($p < 0.4278$) when compared to baseline at time zero. Paired student's t-tests reveal that none of these changes are statistically significant.

Diastolic blood pressure decreased by 8.1 points at 1 month ($p < 0.0034$), 10.1 points at 2 months ($p < 0.0046$), and 10.9 points at 3 months ($p < 0.0004$) when compared to baseline at time zero. Each decrease is statistically significant by paired student's t-test.

No adverse events were observed in any subjects over the course of the study.



Study Limitations

The results of this study suggest that future research based on RS from *Monostroma nitidum* would be worthwhile. This study had a relatively small sample size. Replication in a wider population, with a larger participant group, would be beneficial.

Future research could be conducted to address limitations in this study, namely the small sample size and handling of concomitant medication. In the present study all participants continued to take their present supplements and medications. A randomized controlled trial would also be beneficial. Additionally, a future study may consider measuring nitric oxide or a surrogate marker (e.g. blood nitrite) to validate the hypothesized mechanism of action.

Conclusion

A proprietary dietary supplement which contains the marine-derived compound rhamnan sulfate from *Monostroma nitidum* may reduce diastolic blood pressure, possibly through the action of regenerating the endothelial glycocalyx and thereby supporting endogenous production of the vasodilator nitric oxide. Further study is merited in a wider population.

Disclosures

The study was sponsored by Calroy Health Sciences, LLC., the makers of Arterosil HP®. Calroy was not involved in patient selection, data collection, or statistical analysis of the data. Arterosil HP® was provided by Calroy Health Sciences. Mark Houston, MD is a member of Calroy Health Sciences' Scientific and Medical Advisory Board.

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