Blood Pressure Effects of egg white hydrolysate consumed by Untreated Hypertensive Subjects

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21860

Source
NTR

Brief title
N/A

Health condition

Hypertension, or high blood pressure, is a chronic disease, which can occur early in life, and may lead to other cardiovascular disorders later if not treated. Until recently, hypertension was only directly associated with an increased risk of stroke-related illness. However, it is now known that poor blood pressure control also results in an increased risk of cardiovascular disease in general. Reports have estimated that in uncontrolled or hypertensive patients, 80% of the added risk is for coronary heart disease (CHD), including MI, heart failure, arrhythmias, and cardiac hypertrophy, and 20% is stroke related.
Between 90% and 95% of cases of high blood pressure have no clear cause (essential hypertension). If a cause can be identified, then the initial goal of treatment is to eliminate the underlying cause, otherwise it is treated symptomatically. Consequently, whilst hypertension can be successfully controlled in the vast majority of cases (although this is by no means the case in practice), there is no curative treatment, except perhaps lifestyle modification in certain cases. Many hypertension sufferers will look to other methods to help control blood pressure, particularly their diet. Most patients will remain hypertensive, or on medication and are encouraged to eat a heart healthy diet.

Sponsors and support

Primary sponsor: Bio-Actor BVBA
Technologiepark 3
9052 Gent
Belgium
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

To establish a significant blood pressure reduction by providing subjects with supplements of an egg white hydrolysate.

Secondary outcome

Effect on serum cholesterol levels

Study description

Background summary

N/A

Study objective

The primary objective of this study is to establish a blood pressure reduction by supplementing hypertensive subjects with an egg white hydrolysate (3g of peptides) and measuring the effects against a placebo.

Study design

Six weeks of treatment, six weeks of wash out and six weeks of cross-over treatment.

Intervention

Daily consumption of a single dose of either egg white hydrolysate or placebo over six weeks. After a six weeks of wash out the six week cross-over treatment will be consumed.

Contacts

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Eligibility criteria

Inclusion criteria

1. Blood pressure >130 mm Hg (systolic) and >80 mm Hg (diastolic)

2. Not taking any concomitant medication

3. Otherwise healthy

4. Alcohol consumption <14 units/week for women and <21 units/week for men

5. Aged 35-70 years

Exclusion criteria

1. Participation in any other clinical trial including blood sampling and/or administration of substances up to 90 days before day 1 of this study.

2. Mental status that is incompatible with the proper conduct of the study.

3. Reported unexplained weight loss or gain (>2 kg) in the last month before screening.

4. Females who are pregnant/lactating or planning to become pregnant during the study

period.

5. Have a proven allergy toward egg derived products.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-03-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-03-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1220
NTR-old	NTR1265
Other	: 121920
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

A. Dávalos et.al., Antioxidant activity of peptides derived from egg white proteins by enzymatic hydrolysis, J. Food Prot (2004), 67 (9) 1939-1944.

Miguel. M. et.al., Short-term effect of egg-white hydrolysate products on the arterial blood pressure of hypertensive rats. Br J Nutr. (2005), 94(5):731-7.

Miguel, M. et.al., Long-term intake of egg white hydrolysate attenuates the development of hypertension in spontaneously hypertensive rats, Life Sci., (2005), Dec. 27.

Miguel, M. et.al., Effect of simulated gastrointestinal digestion on the antihypertensive properties of ACE-inhibitory peptides derived from ovalbumin, J Agric Food Chem., (2006), 54(3), 726-731.

Miguel, M. et.al., Vasodilatory effects of peptides derived from egg white proteins, Regulatory peptides, (2007), 140, 131-135.

Miguel, M. et.al., Angiotensin-converting enzyme activity in plasma and tissues of spontaneously hypertensive rats after short- and long-term intake of hydrolysed egg white, Mol. Nutr. Food Res. (2007), 51, 555-563

Miguel, M. et.al. Antihypertensive, ACE-inhibitory and vasodilator properties of an egg white hydrolysate: effect of a simulated intestinal digestion, Food Chemistry (2007), 104, 163-168