

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

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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.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON21860

### Bron

Nationaal Trial Register

### Verkorte titel

N/A

### Aandoening

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.

## Ondersteuning

**Primaire sponsor:** Bio-Actor BVBA

Technologiepark 3

9052 Gent

Belgium

**Overige ondersteuning:** fund=initiator=sponsor

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

N/A

### Doel van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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.

## Contactpersonen

## **Publiek**

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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

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.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	31-03-2008
Aantal proefpersonen:	30
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	29-03-2008
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

## Resultaten

### Samenvatting resultaten

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

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.<br><br>

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.<br><br>

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.<br><br>

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

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<br><br>

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