A randomized, double-blind, placebo controlled, crossover study to determine the effect of 5g egg protein hydrolysate (NWT-03) on arterial stiffness, microcirculation and blood pressure in otherwise healthy subjects with Metabolic Syndrome

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To assess the acute (2h) and short term (2 days and 4 week) effects of daily administration of 5g of NWT03 (an egg-protein hydrolysate) on carotid-radial Pulse Wave Velocity (cr-PWV). Secondary objectives are to assess its effects on carotid-femoral…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON43936

Source
ToetsingOnline

Brief title
NWT03 and arterial stiffness

Condition

- Lipid metabolism disorders

Synonym
Metabolic Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: industrie

Intervention

Keyword: arterial stiffness, egg protein hydrolysate, metabolic syndrome, microcirculation

Outcome measures

Primary outcome

Measurements will be performed at the start and end of each 4-week intervention period. Effects of NWT-03 supplementation will be calculated as the absolute differences between values obtained at each period. The main study endpoint is the change in cr-PWV.

Secondary outcome

Secondary study outcomes are as follows:

* Assess the acute (2 hours) and short term (2 days and 4 week) effects of daily administration of 5g of NWT-03 on carotid femoral Pulse Wave Velocity (cf-PWV)

* Assess the acute (2 hour) and short term (2 days and 4 week) effects of daily administration of 5g dose of NWT-03 on characteristics of microcirculation as measured by fundus photography

* Assess the acute (2 hour) and short term (4 week) effects of daily administration of 5g doses of NWT-03 on Systolic & Diastolic Blood Pressure

* Assess the short term (4 weeks) effects of daily administration of 5g NWT-03 on lipid and lipoprotein metabolism (cholesterol and triacylglycerol levels),

glucose metabolism (glucose and insulin) and incretins (GLP-1, GLP-2, PYY)

Study description

Background summary

Subjects with the metabolic syndrome have an increased risk of developing cardiovascular disease and a twofold risk of developing hypertension. A functional food ingredient with the ability to improve arterial stiffness, microcirculation and/or the ability to reduce blood pressure could potentially contribute to the delay or prevention of a range of cardiovascular diseases and could provide additional complimentary alternatives to pharmacological and lifestyle based interventions in the maintenance of cardiovascular health.

Study objective

To assess the acute (2h) and short term (2 days and 4 week) effects of daily administration of 5g of NWT03 (an egg-protein hydrolysate) on carotid-radial Pulse Wave Velocity (cr-PWV). Secondary objectives are to assess its effects on carotid-femoral PWV, characteristics of microcirculation, systolic and diastolic blood pressure, lipid and lipoprotein metabolism, glucose metabolism and incretins.

Study design

We propose to carry out a randomized, double-blind, placebo controlled crossover study.

Intervention

Group 1 = 5g NWT-03 (Intervention Period 1) * Placebo (Intervention Period 2)
Group 2 = Placebo (Intervention Period 1) * 5g NWT-03 (Intervention Period 2)

Study burden and risks

Before the study starts, subjects will be screened to determine eligibility during a screening visit. During this visit, body weight, height, waist circumference and blood pressure will be measured and a venous blood sample (10 mL) will be collected.

Subjects will return to the site two days after screening 1 for screening 2, a venous blood sample (10 mL) will be collected.

During the study, subjects will receive NWT-03 and placebo powders in random order and are asked to consume it on a daily basis. At visits 3, 4, 5, 6, 7 and 8 (days 0, 2, 27, 56, 58 and 83 of the study), cr-PWV, cf-PWV and office blood pressure will be recorded. A fundus photograph and a blood sample (20mL) will be taken in fasting condition. During the two hours waiting period subjects will perform a four-choice reaction time (RT) task presented on a laptop. And 2 hours after intake of the designated study product cr-PWV, cf-PWV and office blood pressure will again be measured and another fundus photograph will be taken. Additionally, a blood sample (20 mL) will be collected.

Subjects will return after 1 to 2 weeks for a follow up visit, a venous blood sample (20 mL) will be collected.

Thus, in total 332,5 mL blood will be drawn. A pregnancy test will be taken in females of childbearing potential at visits 3 and 6. Subjects will be asked to fill out a food frequency questionnaire and to provide a spot urine sample at visits 3, 5, 6 en 7. Furthermore, subjects will be asked to keep a study diary throughout the duration of the study. Total time investment for the subjects will be approximately 19 hours. Apart from bruises or hematoma, rarely induced by blood sampling, no risks are associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

To be considered eligible for enrolment into the study, subjects must;
1. Be able to give written informed consent,
2. Be between 18 and 75 years of age,
3. Be in generally good health as determined by the investigator,
4. Be non-smokers
5. Have a stable body weight (< 5% change) in the 3 months prior to study entry,
6. Meet the harmonized criteria for the presence of Metabolic Syndrome as agreed by the International Diabetes Federation (IDF), National Heart Lung and Blood Institute, American Heart Association, World Heart Federation, International Atherosclerosis Society and International Association for the Study of Obesity [2], and defined as having at least three of the five following risk factors:
* Central obesity (waist circumference >94cms in males or > 80cms in females) or having a BMI > 30 kg/m2
* Raised triglycerides (>1.7 mmol/L (150mg/dL)
* Reduced HDL cholesterol [<1.03mmol/L (40mg/dL) in males, <1.29mmol/L (50mg/dL) in females]
* Raised fasting plasma glucose > 5.6mmol/L (100mg/dL)
* Raised blood pressure (systolic blood pressure *130 mmHg or diastolic blood pressure *85 mmHg)

Exclusion criteria

Subjects will be excluded from the study if they meet any of the below criteria;
1. Are less than 18 years of age or over 75 years of age,
2. Females who are pregnant, breast feeding or who may wish to become pregnant during the study,
3. Are hypersensitive to any of the components of the test product (i.e. egg protein),
4. Have a significant acute or chronic coexisting illness such as cardiovascular disease, chronic kidney disease (CKD), gastrointestinal disorder, endocrinological disorder, immunological disorder, metabolic disease or any condition which contraindicates, in the investigators judgement, entry to the study,
5. Having a condition or have taken a medication that the investigator believes would interfere with the objectives of the study, pose a safety risk or confound the interpretation of the study results; to include diuretics, blood pressure lowering medication and medication otherwise interfering with renin*angiotensin*aldosterone system (RAAS), such as ACE-

inhibitors, angiotensin receptor blockers, direct renin inhibitors or aldosterone receptor inhibitor and cholesterol lowering agents such as statins.
6. Are taking non-steroidal anti-inflammatory drugs (NSAIDs) within 2 weeks of baseline visit or for the duration of the trial,
7. Suffer from diabetes mellitus, either type I and type II,
8. Consume more than the recommended alcohol guidelines i.e. >21 alcohol units/week for males and >14 units/week for females,
9. History of illicit drug use,
10. Individuals who, in the opinion of the investigator, are considered to be poor attendees or unlikely for any reason to be able to comply with the trial,
11. Subjects may not be receiving treatment involving experimental drugs,
12. If the subject has been in a recent experimental trial, these must have been completed not less than 30 days prior to this study or if the subject has donated blood, at a blood bank, within a period of 8 weeks prior to the start of the study.
13. Have a malignant disease or any concomitant end-stage organ disease,

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2015
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-11-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-02-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-01-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL52607.068.15