The effect of egg protein hydrolysate on arterial stiffness in overweight or moderately obese subjects with impaired glucose tolerance / diabetes type 2

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To assess the short-term (2 hours, and 2 days) effects of the egg protein hydrolysate on arterial stiffness in volunteers, aged 18-70 years with overweight and impaired glucose tolerance (defined as blood glucose >7.0 mmol/l and

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39274

Source
ToetsingOnline

Brief title
Egg protein hydrolysate and vascular function

Condition

- Other condition

Synonym
arterial stiffness

Health condition

vaatflexibiliteit

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Newtricious

Intervention

Keyword: arterial stiffness, egg protein hydrolysate, glucose tolerance, nutrition

Outcome measures

Primary outcome

The main study endpoint will be the change (baseline versus 2 hours, and baseline versus 2 days) arterial stiffness measured as carotid-femoral pulse wave velocity after consumption of the egg protein hydrolysate.

Secondary outcome

Secundary study endpoints will be the changes in plasma glucose and insulin concentrations and calculated HOMA-index, incretins, changes in serum lipids, changes in characteristics of the microcirculation as assessed by fundusphotography, changes in non-invasively assessed upper-arm blood pressure and Sphygmocor-derived central aortic systolic blood pressure and heart rate changes after the use of hydrolysate.

Study description

Background summary

The incidence of type 2 diabetes mellitus (T2DM) is rapidly growing, Patients with T2DM are at increased rik of developing long term micro- and macrovascular complications ; occuring in 40-56% of the T2DM patients in the Netherlands. T2DM accounts for almost one in ten death around the world; up to 80% of these deaths are related to cardiovascular disease. Subjects with impaired fasting

glucose (IFG) or impaired glucose tolerance (IGT) show slightly elevated fasting glucose levels, or increased blood glucose levels after an oral glucose load, respectively, but do not fulfill the criteria of diabetes. Approximately 30% (i.e. 900,000 persons) of the Dutch population over 60 years is thought to have an impaired glucose tolerance, currently more commonly referred to as pre-diabetes. These subjects are generally still considered heatlhy, but do have a markedly increased risk of later development of T2DM.
The development of T2DM can be prevented or delayed by nonpharmacological interventions, in the form of lifestyle modifications such as losing weight, increasing physical activity and a healthy diet. These lifestyle modifications are recommended as step 1 in the treatment of T2DM and IGT in both national and international guidelines. To support these lifestyle changes and proactively reduce the risk of development of T2DM, attempts are also made to modify commonly available foods by removal (of components) or enrichemnt. These so-called functional foods are currently very popular among the population. Recently an ingredient isolated as hydrolysate from egg protein has been experimentally shown to improve the endothelial function. Furthermore, acute ingestion resulted in in vivo studies in mild yet significant inhibition of plasma ACE activity and reduction of blood pressure in spontaneously hypertensive rats. Therefore, this protein hydrolysate is a typical example of an interesting ingredient for the treatment of cardiovascular dysfunction associated with the metabolic syndrome and type 2 diabetes.

Study objective

To assess the short-term (2 hours, and 2 days) effects of the egg protein hydrolysate on arterial stiffness in volunteers, aged 18-70 years with overweight and impaired glucose tolerance (defined as blood glucose >7.0 mmol/l and <11.0 mmol/L, two hours after ingesting 75 gram glucose in 250 ml water) or T2DM.

Study design

A , randomized, double-blind, cross-over design with assessment of effects on the vascular function at baseline, 2 hours and 2 days after oral administration of 5 grams protein hydrolysate or placebo capsules, respectively.

Intervention

The egg protein hydrolysate or placebo (amylum as inert filling material) will be given to the participants in capsules. The subjects will take the hydrolysate or placebo capsules (5 gr/day) on study days 1, 2 and 3 during two periodes seperated by a washout period of minimally two weeks.

Study burden and risks

Before the start of the study, subjects will be screened to determine eligibility; diabetic stability will be determined during an interview and impaired glucose tolerance (glucose > 7.0 mmol/l) will be assessed by an oral glucose tolerance test (only for subjects who are not already diagnosed with T2DM). Upon arrival at the study center in the fasting state, subjects will take a glucose drink and blood will be samples once after two hours to evaluate 2h glucose concentrations. In addition, body weight, height and blood pressure will be measured. The visit lasts approximately 2,5 hours. The study itself includes 4 study days; duration of the first and third day of both periods will be approximately 2,5 hours in the morning. On both days, subjects may not have any food or drinks other than water and their usual medication up till the end of the study session.
In total, the subjects will have nine blood samples taken, i.e. one during the screening process (1 x 3,5 ml) and eight during the study itself (8 x 15 ml) (day 1: fasting, 1h and 2h, and day 3: fasting during each research period). to determine lipid profile, glucose, insulin, incretins, liver and kidney function parameters, HbA1c, and markers of relecting endothelial function and inflammation). Thus the total amount of blood sampled throughout the study is 123,5 ml. On rare occasions, blood sampling might cause bruises or haematoma. Total investment for the subjects (screening plus study) will be approximately 12 hours and 30 minutes.

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

- No allergy to chicken egg protein
- Age between 18 and 70 years
- Male and female
- Body Mass Index (BMI) between 25-35 kg/m2
- Diagnosed T2DM (use of antidiabetic drugs and/or a diabetic diet is allowed) or impaired glucose tolerance (IGT) defined as blood glucose > 7.0 mmol/L and < 11.0 mmol/L, two hours after ingesting 75 gram glucose in 250 mL water

Exclusion criteria

- Active cardiovascular disease like congestive heart failure or recent (< 6 months) event (acute myocardial infarction, cerebral vascular incident)
- Severe medical conditions related to the intestine that might interfere with the study such as inflammatory bowel disease and celiac disease
- Use of insulin
- Use of medication such as RAAS blocking drugs, statins or drugs that change gastric motility or emptying
- Abuse of drugs or alcohol (> 21 units per week)
- Pregnant or breastfeeding women
- Current smoker
- Having donated blood at the blood bank within a period of 8 weeks prior to the start of the study

Study design

Design

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

Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-08-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-11-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	24-02-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-04-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	09-07-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-08-2013
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
Other	-
CCMO	NL36690.068.11

Study results

Date completed:	06-11-2013
Actual enrolment:	40