Effects of alpha-linolenic acid on 24h-ambulatory mean arterial pressure in untreated high-normal and stage I hypertensive subjects

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To study the effects of flaxseed oil, rich in ALA on 24h-ambulatory mean arterial pressure (MAP) in men and women with high-normal blood pressure and mild hypertension compared to high oleic sunflower oil, poor in ALA.

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

Summary

ID

NL-OMON40127

Source
ToetsingOnline

Brief title
VASALA study

Condition

- Lipid metabolism disorders
- Vascular hypertensive disorders

Synonym
High-normal blood pressure, stage I hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Industrie,Unilever

Intervention

Keyword: Alpha-linolenic acid, Blood pressure, n-3 polyunsaturated fatty acids, Vascular function

Outcome measures

Primary outcome

The main study parameter is the change in 24h-ambulatory mean arterial pressure

(MAP)

Secondary outcome

The secondary objectives are to study the effects of flaxseed oil on 1) night,

day and early morning 24h-ambulatory MAP, 2) systolic, diastolic and MAP office

blood pressure, 3) postprandial flow mediated dilatation (FMD) and 4) the

fatty-acid profile of plasma phospholipids

Study description

Background summary

Increased intakes of n-3 long chain polyunsaturated fatty acids eicosapentanoic acid (EPA) and docosahexaenoic acid (DHA), mainly found in fatty fish, are recommended for the prevention of coronary heart disease. Alpha-linolenic acid (ALA, C18:3n-3) is the most common vegetable-oil based n-3 fatty acid. Evidence exists that ALA supplementation can also have a protective effect on the development on cardiovascular disease, but may exert its cardioprotective effects through different routes. The benefit may (partly) be due to blood pressure lowering. However, evidence for beneficial effects of ALA on blood pressure is conflicting. Therefore, we propose to investigate the effect of flaxseed oil, high in ALA, using a study powered on 24-hour blood pressure, in a population with high normal blood pressure and mild hypertension.

Study objective

To study the effects of flaxseed oil, rich in ALA on 24h-ambulatory mean arterial pressure (MAP) in men and women with high-normal blood pressure and mild hypertension compared to high oleic sunflower oil, poor in ALA.

Study design

Using a double blind randomized, placebo-controlled parallel design, subjects will receive at random daily 10 g of flaxseed oil or a high-oleic acid sunflower oil (HOSF) as control for twelve weeks, with a run-in period of 14 days in advance.

Intervention

During the run-in period, subjects will receive daily 10 g of palm super olein oil. During the intervention period subjects receive either 10 ml of high oleic sunflower oil or flaxseed oil. All oils are provided in bottles of 5 g, on will be consumed at breakfast or lunch and one at dinner.

Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during one 15 and one 10 min visit. During these visits, body weight, height and blood pressure will be measured and a blood sample (5.5 mL) will be drawn by means of venapunction.
During the run-in period of two weeks, subjects will receive palm super olein oil and during the intervention period of twelve weeks they will receive at random, HOSF or flaxseed oil. On six occasions a fasting blood sample will be drawn (with a total of 50 mL spread over the six visits), body weight and blood pressure will be measured. In addition, during week 2 and 6, a retinal image will be taken and pulse wave velocity measurements will be performed to assess vascular function. Also 24-h blood presseure measurements will be performed, this can disturb daily activities because they have to be interrupted when the measurement is performed.
A subset of 40 subjects will participate in a postprandial test. An intravenous cannula will be inserted in an antecubital vein. Before and after meal consumption, nine blood samples (67.5 mL) will be drawn over 4.5 hours and flow mediated dialation (FMD) will be measured.
All subjects will be asked to fill out a food frequency questionnaire two times and to keep a study-diary throughout study. On rare occasions, blood sampling might cause bruises or hematoma. Total time investment for the subjects will be approximately 6.5 hours and an extra 4.5 hours if they participate in the postprandial test.

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

- Aged between 40-70 years
- Quetelet-index between 25-35 kg/m2
- High-normal blood pressure or stage I hypertension
- Mean serum total cholesterol < 8.0 mmol/L
- Mean serum triacylglycerol < 4.5 mmol/L
- Mean plasma glucose < 7.0 mmol/L

Exclusion criteria

- Unstable body weight (weight gain or loss >2 kg in the past 3 months)
- Use of antihypertensive or anticoagulant medication

- Indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
- Usage of non-steroidal anti-inflammatory drugs (aspirin, ibuprofen, naproxen) and not able or willing to stop taking them from at least 4 weeks prior to the study
- Use of medication or a diet known to affect serum lipid or glucose metabolism
- Women taking oral contraceptives or estrogen replacement therapy
- Women lactating, pregnant or intend to become pregnant during study
- Active cardiovascular disease like congestive heart failure or recent (<6 months) event (acute myocardial infarction, cerebro vascular accident)
- Severe medical conditions that might interfere with the study such as diabetes mellitus, epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel diseases and rheumatoid arthritis
- Smoking
- Abuse of drugs
- More than 21 alcohol consumptions per week for men and 14 consumptions for women
- Reported intense sporting activities > 10 h/w
- Not possible or difficult to venipuncture as evidenced during the screening visits
- Use of an investigational product within the previous 30 days
- Not willing to stop the consumption of vitamin supplements, fish oil capsules or products rich in plant stanol or sterol esters 3 weeks before the start of the study
- Not willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study and during the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-06-2014
Enrollment:	144

Type:	Actual

Ethics review

Approved WMO Date:	16-04-2014
Application type:	First submission
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	NL47452.068.13