The effects of beetroot juice on postprandial vascular activity after a high-fat meal in overweight and slightly obese men

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The objective of the study is to investigate the effects of beetroot juice, a high nitrate-containing vegetable, on postprandial vascular activity after a high-fat load in overweight and slightly obese male subjects.

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

Summary

ID

NL-OMON37598

Source
ToetsingOnline

Brief title
Beetroot juice and postprandial vascular activity

Condition

- Lipid metabolism disorders

Synonym
insulin resistance syndrome, Metabolic Syndrome, Syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: TI Food and Nutrition

Intervention

Keyword: beetroot juice, nitrate, postprandial state, vascular activity

Outcome measures

Primary outcome

The primary parameter is the capacity of vessels to respond to a standardized high-fat meal during the postprandial period as assessed with flow-mediated dilation (FMD) of the brachial artery.

Secondary outcome

Secondary study endpoints are the responsiveness of larger arteries to postprandial lipemia measured by pulse wave analysis (PWA) and pulse wave velocity (PWV). Microcirculatory effects will be visualized by retinal imaging. In plasma, metabolic risk markers related to the metabolic syndrome will be investigated: postprandial concentrations of factors related to low-grade inflammation and endothelial activation, and postprandial lipid and glucose metabolism. Finally, effects on blood pressure and heart rate will be studied.

Study description

Background summary

Increased postprandial lipemia may increase the risk for cardiovascular diseases. An important mechanistic link between lipemia following a high-fat meal and adverse cardiovascular events is lipid-mediated endothelial activation. Therefore, it is important to identify nutrients that can neutralize this acute vascular disturbance. We hypothesize that beetroot juice, a food rich in inorganic nitrate, could improve vascular activity during the postprandial phase.

Study objective

The objective of the study is to investigate the effects of beetroot juice, a high nitrate-containing vegetable, on postprandial vascular activity after a high-fat load in overweight and slightly obese male subjects.

Study design

Using a randomized crossover design, subjects will receive in random order two different interventions with a washout period of at least 7 days. During each test, the postprandial response is measured.

Intervention

Subjects will receive beetroot juice or an isocaloric carbohydrate drink as control on two separate occasions. The drinks will be provided with two muffins providing 56.6 g fat.

Study burden and risks

Before the start of the study subjects will be screened to determine eligibility during two visits of respectively 15 and 10 minutes. During these visits, body weight, height, waist circumference and blood pressure will be measured and a venous blood sample (3.5mL) will be drawn. Following screening, subjects will be asked to attend the research facilities at Maastricht University, on two separate occasions. During these visits, an intravenous cannula will be inserted in an antecubital vein. Before and after meal consumption, nine blood samples (79.5 mL each day) will be drawn over the next four hours. In total, 166 mL of blood will be sampled (2 x 3.5 mL during screening and 2 x 79.5 mL during the study). During the day, two retinal photographs will be taken. Vascular activity and function measurements, i.e. FMD, PWA and PWV, are performed before and after meal consumption. Total time investment for the subjects will be approximately 745 minutes. During this period, subjects will remain at the university. On rare occasions, blood sampling might cause bruises or haematoma.

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

Healthy overweight and slightly men will be included. Further inclusion criteria are:
- Aged between 18 and 70 years
- Quetelet-index between 28 and 35 kg/m2
- Mean serum triacylglycerol <=1.7 mmol/L

Exclusion criteria

- Women
- Quetelet-index between <28 or >35 kg/m2
- Mean serum triacylglycerol >=1.7 mmol/L
- Indication for treatment with cholesterol-lowering drugs according to the Dutch Cholesterol Consensus
- Current smoker
- Diabetic patients or individuals receiving antidiabetic medication
- Familial hypercholesterolemia
- Abuse of drugs
- More than 21 alcoholic consumptions per week
- Unstable body weight (weight gain or loss >3 kg in the past three months)
- Use of use of medication known to affect serum lipid metabolism
- No severe medical conditions that might interfere with the study.

Severe medical conditions are:
a high blood pressure, epilepsy, asthma, allergies, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis.
- Active cardiovascular disease like congestive heart failure or recent (<6 months) event (acute myocardial infarction, cerebro vascular accident)
- Use of an investigational product within the previous 1 month
- Not willing to stop the consumption of foods rich in nitrates 3 weeks before the start of the study.
Foods rich in nitrates are:
beets, celery, radishes, turnips and spinach.
- Not willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study
- Not or difficult to venipuncture as evidenced during the screening visits

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2012
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	05-03-2012
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-04-2012
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	NL39114.068.11

Study results

Date completed:	30-08-2012
Actual enrolment:	21