Comparison of flow-mediated dilatation with local thermal hyperaemia as a measure of endothelial function.

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The main objective of our study is to explore whether LTH and FMD are correlated. Main secondary objectives are to investigate whether the LTH response is largely NO-mediated and whether drinking beetroot juice acutely improves both FMD and LTH.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40563

Source
ToetsingOnline

Brief title
BeeJEM

Condition

- Other condition

Synonym
Endothelial dysfunction

Health condition

Bloedvataandoeningen; endotheel dysfunctie

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,NWO;Vidi subsidie,Unilever,Unilever sponsort

Intervention

Keyword: Beetroot juice, Endothelial function, FMD, LTH

Outcome measures

Primary outcome

Degree of correlation between FMD and LTH

Secondary outcome

Involvement of NO in LTH response

Changes in FMD and LTH in response to beetroot juice consumption

Study description

Background summary

Measurement of flow-mediated dilatation of the brachial artery in response to forearm occlusion for 5 min (FMD) using ultrasonography is a well-accepted, but investigator-demanding method, to determine endothelial function. Local thermal hyperaemia of the skin measured with a laser Doppler flow imaginer (LTH) is less demanding and may be a suitable alternative to determine endothelial function at frequent intervals. We want to investigate whether LTH correlates with FMD response in a group of healthy non-smoking and smoking men and to what extent LTH can be inhibited by the nitric-oxide synthase (NOS) inhibitor L-NMMA applied locally on the skin. In addition we want to replicate the reported improved FMD response to nitrate-rich beetroot juice and correlate this to the LTH response. Post occlusive reactive hyperaemia (PORH) of the skin is considered to be a measure of microvascular function and is also thought to be correlated to the FMD response. We will also determine the PORH response during this study.

Study objective

The main objective of our study is to explore whether LTH and FMD are

correlated. Main secondary objectives are to investigate whether the LTH response is largely NO-mediated and whether drinking beetroot juice acutely improves both FMD and LTH.

Study design

Randomised, double-blind, placebo-controlled cross-over study

Intervention

Beetroot juice and placebo.

Study burden and risks

All the techniques applied are non-invasive and without risk and only provide minimal discomfort related to the 5 minute lasting arterial occlusion of the forearm by a blood pressure cuff and the dietary ristrictions. Participants have to visit our research department twice for FMD and LTH measurements. For their time investment they will be reimbursed. The intervention with commercially available beetroot juice (Beet-it) or placebo is not associated with any risk.

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

Non-smokers:
- Healthy Men
- Age between 25-65 years
- Non-smoking for > 5 years
- Body mass index between 18 and 30 kg/m2
- Capable and willing to give informed consent
- General good health, based on medical history and physical examination
- Systolic BP measured on day of the experiment should be < 160 mmHg;Smokers:
- As for the non-smokers
- In addition smoking at least on average 14 cigarettes per day for at least 5 years

Exclusion criteria

- female subjects
- History of cardiovascular disease
- Use of vasoactive drugs
- Drug or/and alcohol abuse

Study design

Design

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

Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2014
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28932
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45250.078.13
OMON	NL-OMON28932