The effect of nutritional intervention on postprandial skeletal muscle microcirculation in obese subjects

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To investigate whether the intake of a single dose of nitrate-rich beetroot juice or a flavonoid-rich black tea causes an increase of post-prandial muscle blood flow in obese insulin resistant subjects

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37094

Source
ToetsingOnline

Brief title
Tea-Beetroot-VOP

Condition

- Other condition

Synonym
obesity and insulin resistance

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Unilever
Source(s) of monetary or material Support: Unilever BV

Intervention

Keyword: beetroot juice, obesity, postprandial, tea

Outcome measures

Primary outcome

Peripheral vascular resistance after a 75 gr glucose load combined with water/tea/beetroot juice, where vascular resistance is calculated as the product of blood flow as measured by venous occlusion plethysmography and arterial blood pressure by the Finapress (in mmHg/100 mL tissue/min). The area-under-the-curve of the peripheral vascular resistance in the forearm and leg is calculated up to 3 h after the glucose load.

Secondary outcome

NA

Study description

Background summary

Skeletal muscle is the principal tissue responsible for insulin-stimulated glucose disposal and therefore plays an important role in the postprandial regulation of glucose levels. Impaired glucose transport in skeletal muscle, such as present with obesity, leads to impaired whole body glucose uptake. Indeed, obesity is associated with an impaired postprandial increase in skeletal muscle blood flow. The lower postprandial blood flow may contribute to the impaired glucose homeostasis. Restoring glucose disposal may therefore be induced by improving skeletal muscle blood flow and vascular function. Based on in vitro and in vivo, previous studies found that flavonoid-rich and nitrate-rich food products improve vascular function. Therefore, these food products may improve postprandial blood flow responses in obese subjects.

In the present study, muscle perfusion will be studied before and after an oral glucose challenge following a fasting period, which will induce an insulin-dependent increase in muscle blood flow and glucose metabolism. Based on data from previous studies, this physiological response is blunted in obese subjects, and we expect these responses to be restored when the glucose load is combined with tea or beetroot juice.

Study objective

To investigate whether the intake of a single dose of nitrate-rich beetroot juice or a flavonoid-rich black tea causes an increase of post-prandial muscle blood flow in obese insulin resistant subjects

Study design

randomised, placebo-controlled, cross-over study

Study burden and risks

The flavonoid-rich tea fraction is derived from ordinary brewed black tea and thus considered harmless. The second intervention is Beet-It beetroot juice (James White Drinks Ltd.), which is a commercially available drink and also considered harmless.
Prior to the 3 visit days, subjects have fasted since the evening before the visit. As all subjects are considered to be healthy, we expect no health problems or problems with the overnight fast period. All vascular function measurements are non-invasive. For blood analyses, repeated venous blood samples (7 X 10 mL) will be taken from an intra-venous catheter in the forearm. Insertion of the catheter is associated with a 5% risk for haemorrhage, which will result in a full recovery within 2 weeks. Subjects will ingest 75 grams of glucose, which is the amount that is used in the very widely applied Oral Glucose Tolerance Test, and therefore not expected to cause any harm to the subject. Participants do not directly benefit from study participation.

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

- Male sex
- Aged 30-70 years
- Obesity (>30 kg/m2)
- insulin resistance as fasting glucose levels >6.1 mmol/L
- Reported intense sport activities <=10 h/w
- Reported alcohol consumption <=28 units/w
- Agreeing to be informed about medically relevant personal test-results by a physician
- Signed Informed consent
- Currently not smoking and being a non-smoker for at least 3 months prior to the start of the study

Exclusion criteria

- BMI >=40 kg/m2
- Presence of cardiovascular disease
- Presence of sudden cardiac death in a 1st degree relative at an age <50 years
- Presence of diabetes mellitus type 2
- Regular tea drinker (> 2 cups per day)29
- Prescribed medical treatment that may affect the cardiovascular system
- Reported use of any medically- or self-prescribed diet
- Reported weight loss or gain >10% during a period of 6 months prior to the study

- Subjects who participated in studies with a drug and/or nutritional intervention and without risks for carry-over effects are excluded for 1 month from participation in this study
- Reported participation in night shift work two weeks prior to the study or during the study (defined as working between midnight and 6.00 am)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-12-2012
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	12-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41626.091.12

Study results

Date completed:	02-05-2013
Actual enrolment:	16