Can heating prevent hyperglycaemia-induced endothelial dysfunction?

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To examine whether heating can prevent the hyperglycaemia-induced decline in endothelial function in T2DM and age- and sex-matched controls.

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

Summary

ID

NL-OMON38281

Source
ToetsingOnline

Brief title
Heating, hyperglycaemia and endothelial dysfunction

Condition

- Diabetic complications

Synonym
impaired vessel function after a meal, post-prandial endothelial dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: blood flow, diabetes mellitus type 2, endothelial function, hyperglycaemia

Outcome measures

Primary outcome

The change in endothelial function after 75-gr glucose (measured as the

brachial artery flow-mediated dilation at 3 distinct time-points).

Secondary outcome

blood flow (in mL/min)

Study description

Background summary

Endothelial dysfunction contributes to the development of vascular complications in type 2 Diabetes Mellitus (T2DM). Elevation in glucose level (i.e. hyperglycaemia) is demonstrated to contribute to a transient decrease in endothelial function, especially in T2DM as these subjects demonstrate prolonged hyperglycaemia after a glucose load compared to healthy controls.

In previous studies, we have demonstrated that elevation in blood flow can improve endothelial function in healthy subjects. Accordingly, elevation in blood flow may also counteract the impact of hyperglycaemia on endothelial function in T2DM and their age- and sex-matched controls.

Study objective

To examine whether heating can prevent the hyperglycaemia-induced decline in endothelial function in T2DM and age- and sex-matched controls.

Study design

Cross-sectional observational study

Study burden and risks

We will take a total of four venous blood samples from each subject. Taking a blood sample is associated with a 5% risk of developing a haemorrhage, which is not associated with any functional limitations and will disappear within 2 weeks. To minimise the potential risk, a venous *line* is introduced once which facilitates repeated venous blood withdrawals. Other measures/interventions (75

gr glucose load, heating, echo-Doppler, 5-minutes cuff inflation) are not associated with any potential health 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

Diabetes group:
- Older than 40 years
- Diagnosed with type 2 diabetes mellitus at least 2 years ago
Control group:
- Older than 40 years

Exclusion criteria

Diabetes group:
- Women
- Cardiovascular disease
- Hypercholesterolemia
- Hypertension (>160 mmHg systolic and/or >90 mmHg diastolic pressure) and/or subjects on antihypertensive drugs
- Smoking
- Type I diabetes mellitus
- Older than 70 years
- Subjects with vascular complications due to type 2 diabetes mellitus (e.g. diabetic foot ulcer);Control group:
- Women
- Cardiovascular disease
- Hypercholesterolemia
- Hypertension (>160 mmHg systolic and/or >90 mmHg diastolic pressure) and/or subjects on antihypertensive drugs
- Smoking
- Older than 70 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-01-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	24-12-2013
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	NL47169.091.13

Study results

Date completed:	03-07-2014
Actual enrolment:	20