Kan warmte post-prandiale endotheel dysfunctie voorkomen?

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26610

Source

Brief title OGTT-heat

Health condition

post-prandiale endotheel dysfunctie

Sponsors and support

Primary sponsor: Radboud university medical centre Source(s) of monetary or material Support: Unilever BV +sponsor

Intervention

Outcome measures

Primary outcome

Change in endothelial function (measured as flow-mediatd dilation) after a meal (induced by 75-gr glucose ingestion)

Secondary outcome

Study description

Background summary

Rationale:

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 agematched controls.

Objectives:

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

Study design:

Cross-sectional observational study

Study population:

10 subjects with T2DM and 10 age -matched controls

Intervention (if applicable):

Not applicable

Main study parameters/endpoints:

The change in endothelial function after 75-gr glucose (measured as the brachial artery flowmediated dilation at 3 distinct time-points).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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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.

Study objective

Warmte zorgt voor toename van de doorbloeding, welke lokaal een afname van de endotheelfunctie na een maaltijd kan voorkomen.

Study design

Before and after (1, 2 and 2.5 h) 75-gr glucose

Intervention

Local heating

Contacts

Public

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Eligibility criteria

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 (ensure matching with diabetes group at group level)

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)

- Subjects using insulin injections to regulate glucose homeostasis

Control group:

- Women
- Cardiovascular disease
- Hypercholesterolemia

- Hypertension (>160 mmHg systolic and/or >90 mmHg diastolic pressure) and/or subjects on antihypertensive drugs

- Smoking

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	20
Туре:	Anticipated

Ethics review

Not applicable Application type: Not applicable

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.

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In other registers

Register	ID
NTR-new	NL4513
NTR-old	NTR4631
Other	CMO: 2013-536

Study results