

Optimising the effects of exercise in diabetes

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We will identify factors that interfere with the beneficial effects of exercise on the vasculature in T2DM.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON36171

Source

ToetsingOnline

Brief title

OPT-EX-D

Condition

- Coronary artery disorders
- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Diabetes

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: cardiovascular disease, diabetes, endothelial function, exercise

Outcome measures

Primary outcome

The effect of an increase in the exercise-induced shear stress on the post-exercise endothelial function (as measured with the brachial artery flow-mediated dilation) in subjects with T2DM

The effect of hyperglycaemia on post-exercise endothelial function (as measured with the brachial artery flow-mediated dilation) in T2DM.

Secondary outcome

Not applicable

Study description

Background summary

Endothelial dysfunction contributes to the development of vascular complications in type 2 Diabetes Mellitus (T2DM). Exercise training improves endothelial function, and in this improving process shear stress is a key factor. T2DM show an impaired shear stress to exercise. This prevents an optimal effect of training, which may be restored by increasing the exercise-induced shear stress.

Shear stress leads to the production of nitric oxide, a strong dilator with anti-atherogenic effects. Hyperglycaemia impairs the shear stress signaling pathway, leading to a smaller NO production and preventing the beneficial effects of exercise on the endothelial function in T2DM.

Study objective

We will identify factors that interfere with the beneficial effects of exercise on the vasculature in T2DM.

Study design

Cross-sectional observational study

Study burden and risks

5 minutes of cuff occlusion will be employed to investigate endothelial function. This is a non-invasive procedure and is not associated with any health risks for the subject. We will also take three venous blood samples from each subject. Subjects will perform a hand grip protocol, which can be somewhat tiring, but is not associated with any health risks for the subject. Local heating of the forearm (42°C) will be employed, and furthermore, 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. Subjects do not benefit directly from participating in this study.

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

Older than 40 years

Diagnosed with type 2 diabetes mellitus at least 2 years ago

Exclusion criteria

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 65 years

Subjects with vascular complications due to type 2 diabetes mellitus (e.g. diabetic foot ulcer)

Study design

Design

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

Recruitment

NL	
Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date: 10-05-2011

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	NL36179.091.11