# **Optimising the effects of exercise in diabetes**

Published: 10-05-2011 Last updated: 28-04-2024

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 furtermore, 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

#### Public

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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
Туре:	Anticipated

# **Ethics review**

Approved WMODate:10-05-2011Application type:First submissionReview 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 CCMO ID NL36179.091.11