

Effect of exercise training on fat distribution in patients with type 2 diabetes

Submission date 25/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 08/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/04/2011	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P10.018

Study information

Scientific Title
Effect of exercise training on ectopic fat accumulation in patients with type 2 diabetes

Study objectives
Determining the effect of an exercise program on ectopic fat accumulation in heart, liver and skeletal muscle

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethics Committee of Leiden University Medical Center approved on 19/02/2011 ref: protocol number: P10.018

Study design

Open prospective intervention study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions

Patients are studied before and after a six month exercise intervention

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Visceral and subcutaneous abdominal fat volume
2. Myocardial, myocellular and hepatic triglyceride content
3. Epi- and pericardal fat volume

Key secondary outcome(s)

1. Cardiac function
2. Anthropometric measures (weight, blood pressure)
3. Energy intake and expenditure
4. Metabolic parameters (HbA1c, lipid levels from blood plasma)

Completion date

01/01/2011

Eligibility**Key inclusion criteria**

1. Ages of 18 - 70 years
2. Diagnosis of type 2 diabetes mellitus

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Complications of diabetes (retinopathy, neuropathy, nephropathy)
2. Hypertension (systolic blood pressure > 165 mmHg and/or diastolic blood pressure > 95 mmHg)
3. Body mass index (BMI) > 35kg/m²
4. Smoking
5. Cardiac diseases
6. Claustrophobia or any other contra-indication for magnetic resonance imaging (MRI)

Date of first enrolment

24/02/2010

Date of final enrolment

01/01/2011

Locations**Countries of recruitment**

Netherlands

Study participating centre

Albinusdreef 2

Leiden

Netherlands

2333 ZA

Sponsor information**Organisation**

Leiden University Medical Center (Netherlands)

ROR

<https://ror.org/05xvt9f17>

Funder(s)

Funder type

Research organisation

Funder Name

Center for Translational Molecular Medicine (Netherlands) (grant 01C-104)

Funder Name

Netherlands Heart Foundation (Netherlands)

Funder Name

Dutch Diabetes Research Foundation (Netherlands)

Alternative Name(s)

Dutch Diabetes Research Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Dutch Kidney Foundation (Netherlands)

Alternative Name(s)

Dutch Kidney Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Bas van de Goor Foundation (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes