

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

Contact name
Dr Eelco De Koning

Contact details
Albinusdreef 2
Leiden
Netherlands
2333 ZA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

24/02/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

14

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)

Sponsor details

Albinusdreef 2

Leiden

Netherlands

2333 ZA

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration