ISRCTN26977705 https://doi.org/10.1186/ISRCTN26977705

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

Submission date	Recruitment status	[ ] Prospectively registered
25/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2011	Nutritional, Metabolic, Endocrine	[ ] 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

Primary study design
Interventional

Study design
Open prospective intervention study

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