

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

<b>Submission date</b> 25/03/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/04/2011	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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**  
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**Contact details**  
Albinusdreef 2  
Leiden  
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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/m<sup>2</sup>
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