Effects of a 6-month exercise program on ectopic fat accumulation in heart, liver and skeletal muscle in patients with type 2 diabetes mellitus.

Published: 22-02-2010
Last updated: 10-08-2024

-Determination of the effects of an exercise program on ectopic fat accumulation in heart, liver and skeletal muscle-To assess the relationship between metabolic and inflammatory parameters with changes in MRI outcome-To assess the differences in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON34635

Source
ToetsingOnline

Brief title
Exercise and ectopic fat accumulation

Condition

- Heart failures
- Diabetic complications
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Isala Klinieken Zwolle;onderzoeksfonds prof. Bilo

Intervention

Keyword: diabetes mellitus type 2, ectopic fat, exercise

Outcome measures

Primary outcome

Hepatic, myocardial and muscle triglyceride content and cardiac function

Secondary outcome

Antropometric measurements, biochemical values and basal metabolic rate.

Study description

Background summary

Background
Ectopic fat accumulation is common in type 2 diabetes and is associated with insulin resistance, a worsening of glycemic control, lipid abnormalities and increased risk for cardiovascular disease. It occurs in heart, liver and skeletal muscle. Life style changes are a pillar of therapy. Although changes in diet could have beneficial effects on ectopic fat accumulation, this is less clear during exercise training. It is also unclear how ectopic fat deposits in different organs relate to each other at baseline and during the exercise program.

Study objective

-Determination of the effects of an exercise program on ectopic fat accumulation in heart, liver and skeletal muscle
-To assess the relationship between metabolic and inflammatory parameters with changes in MRI outcome
-To assess the differences in ectopic fat accumulation in female diabetic patients and female healthy controls at baseline

Study design

Open, prospective intervention study with duration of 6 months

Intervention

Exercise program during 6 months
All patients will receive an individualised exercise program. Every month patients will report the amount of exercise, details on diet and they will carry the SenseWear during this week to measure caloric consumption. Each patient will have a coach.

The healthy controles will only get a baseline MRI-scan, but no intervention

Study burden and risks

The individualised exercise program stimulates patients to exercise 5 times a week for minimal 30 minutes per training. This program including a coach, does not cost the patients extra money.
The burden of the study includes the two MRI-scans, during which patients have to lie still. We expect no harmful effects of the MRI-scan, if contra-indications are carefully checked.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA LEIDEN
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
2333 ZA LEIDEN
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Group A: Diabetes mellitus type 2, Age>18 years, informed consent
Group B: Age and BMI matched female healthy controls, Age >18 years, informed consent

Exclusion criteria

Group A: (congenital) heart disease; liver disease (increased ALAT and GGT); renal disease (creatine above reference level); muscular diseases; BMI > 36 kg/m2; MRI contra-indications;Group B: same as group B + no diabetes mellitus + no pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2010
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	22-02-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	ID
CCMO	NL31412.058.10