Short and long term effect of a Very Low Calorie Diet (VLCD) with or without exercise in obese insulin-dependent type 2 diabetes mellitus patients

Submission date	Recruitment status	Prospectively registered
23/02/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/04/2011	Completed	[X] Results
Last Edited	Condition category	Individual participant data
16/07/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

P05-033

Study information

Scientific Title

Short and long term effect of a Very Low Calorie Diet (VLCD) with or without exercise in obese insulin-dependent type 2 diabetes mellitus patients: A randomised controlled trial

Study objectives

- 1. The addition of exercise to a 16-week VLCD will normalise insulin sensitivity
- 2. The addition of exercise to a 16-week VLCD will further improve insulin signalling in the skeletal muscle cell
- 3. The addition of exercise to a 16-week VLCD improve quality of life insulin sensitivity long-term
- 4. The addition of exercise to a 16-week VLCD improve low-grade inflammation long-term
- 5. Prolonged caloric restriction will improve ectopic fat depositions in the heart, liver and pericardium

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical ethical committee of the Leiden University Medical Hospital, 08/06/2005

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus type 2

Interventions

One patients group followed a 16-week very low calorie diet.

The other patient group followed a 16-week very low calorie diet combined with an exercise program, which consisted of a one hour in-hospital training weekly, primarily aerobic exercise, under supervision of a physiotherapist. Also four training sessions at home on a cyclo-ergometer for 30 minutes at 70% of maximum aerobic capacity.

Measurements were performed at baseline, directly after the 16-week intervention and 18 months after start of the intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

- 1. Insulin sensitivity (as measured by hyperinsulinaemic euglycemic clamp)
- 2. Insulin signalling (measured in muscle biopsies)
- 3. Mitochondrial copy number (measured in muscle biopsies)
- 4. Low grade inflammation (measured in fasting blood samples)
- 5. Quality of Life (as measured by four different QoL questionnaires)
- 6. Ectopic fat depositions (as measured by magnetic resonance proton spectroscopy)

Key secondary outcome(s))

Long-term effects

Completion date

01/09/2009

Eligibility

Key inclusion criteria

- 1. Type 2 diabetes mellitus patients
- 2. Body mass index (BMI) > 30 kg/m2 (but weight has to be greater than 90 kg to sustain a 16 week VLCD)
- 3. Age > 30 years
- 4. Use of at least 30 units of insulin/day with or without oral blood glucose lowering agents
- 5. Fasting c-peptide level > 0.8 ng/l and a two times rise on 1 mg glucagon (intravenous) IV

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

- 1. No residual insulin secretory capacity as defined by no response to a glucagon stimulation test
- 2. Weight above 130 kg and fasting plasma glucose >15 mmol/l
- 3. Any significant chronic disease
- 4. Renal, hepatic or another endocrine disease
- 5. Use of medication known to influence lipolysis and/or glucose metabolism
- 6. Recent weight changes or attempts to lose weight (> 3 kg weight gain or loss, within the last 3 months)
- 7. Difficulties to insert an intravenous catheter
- 8. Smoking
- 9. Severe claustrophobia (ventilated hood)
- 10. Recent blood donation (within the last 3 months)
- 11. Recent participation in other research projects (within the last 3 months), participation in 2 or more projects in one year
- 12. Pregnancy
- 13. Disease interfering with the use of a thiazolidinediones (TZD) (heart failure, oedema, liver function abnormalities) or participating in regular exercise

Date of first enrolment

01/05/2005

Date of final enrolment

01/09/2009

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

Hospital/treatment centre

Funder Name

Leiden University Medical Center (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

Results article	results	21/11/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes