

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 23/02/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/04/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/07/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

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 measure

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)

Secondary outcome measures

Long-term effects

Overall study start date

01/05/2005

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

Age group

Adult

Sex

Both

Target number of participants

28

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)

Sponsor details

Albinusdreef 2

Leiden

Netherlands

2333 ZA

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/05xvt9f17>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leiden University Medical Center (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/11/2014		Yes	No