

Effects of a very low calorie diet in type 2 diabetes.

No registrations found.

| | |
|------------------------------|------------------|
| Ethical review | Positive opinion |
| Status | Recruiting |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON24965

Source

NTR

Brief title

VLCD

Health condition

Diabetes mellitus type 2
Cardiovascular complications
Adiposity/obesity

Sponsors and support

Primary sponsor: Leiden University Medical Center

Source(s) of monetary or material Support: The Netherlands heart foundation

Intervention

Outcome measures

Primary outcome

1. Heart function: Systolic and diastolic;
2. Myocardial triglyceride content;

3. Heart dimensions.

Secondary outcome

1. Glucose tolerance;
2. Body fat distribution;
3. Pulse wave velocity;
4. Liver triglyceride content.

Study description

Background summary

Rationale:

Type 2 diabetes mellitus (DM2) is caused by profound disturbances in glucose and lipid metabolism, ultimately resulting in progressive atherosclerosis and microangiopathy.

In previous studies we have documented the metabolic and functional effects of dietary interventions on the heart in healthy subjects and patients with DM2 without overt cardiac complications. We hypothesize that dietary interventions also decrease myocardial TG stores and improve cardiac function in patients with DM2 and cardiovascular complications. This will open perspectives for dietary interventions which decrease myocardial TG stores and improve myocardial dysfunction in this category of patients.

Study objective

We hypothesize that a very low calorie diet decreases myocardial TG stores and improves myocardial dysfunction in patients with DM2 and cardiovascular complications.

Study design

Very low calorie diet for 16 weeks. Patients have a MRI scan before and after the diet to assess heart function, myocardial triglyceride content, etc. 18 months after start of the diet, patients will have a third MRI.

Intervention

Our patients follow a very low calorie diet for 16 weeks. Just before and just after the diet patients will undergo a MRI. With this MRI we assess cardiac function, myocardial/hepatic

triglycerides, subcutaneous and visceral fat and aortic stiffness.

The VLCD will consist of a total meal replacement (400-600 calories a day) of Prodimed. This will be expanded after 3 weeks and again after 6 weeks (guided by BMI). Participants will be seen every week to control bloodsugar, weight and bloodpressure. Participants are stimulated to continue the intervention.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

1. Diabetes mellitus type 2;
2. BMI > 25 kg/m² and maximum 150 kg;
3. Age > 18 years and < 70 years;
4. Cardiovascular complications: Percutaneous Coronary Intervention (PCI) in medical history and/or >50% occlusion on coronary CT;
5. NYHA class 1 and 2;
6. EGFR > 60 ml/min.

Exclusion criteria

1. Any significant chronic disease, except diabetes mellitus type 2;
2. Renal, hepatic or another endocrine disease;
3. Signs of a septal myocardial infarction;
4. Difficulties to insert an intravenous catheter;
5. Severe claustrophobia;
6. Recent participation in other research projects (within the last 3 months), participation in 2 or more projects in one year;
7. Pregnancy;
8. Congenital heart disease;
9. MRI contra-indications.

Study design

Design

| | |
|---------------------|-------------------------|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-04-2011 |
| Enrollment: | 30 |
| Type: | Anticipated |

Ethics review

Positive opinion

Date: 10-05-2011

Application type: First submission

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 |
|----------|-------------------------------------|
| NTR-new | NL2758 |
| NTR-old | NTR2897 |
| Other | METC LUMC : P10.188 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

Study results

Summary results

N/A