

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24965

Bron

NTR

Verkorte titel

VLCD

Aandoening

Diabetes mellitus type 2
Cardiovascular complications
Adiposity/obesity

Ondersteuning

Primaire sponsor: Leiden University Medical Center

Overige ondersteuning: The Netherlands heart foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Heart function: Systolic and diastolic;

2. Myocardial triglyceride content;

3. Heart dimensions.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

LUMC, Albinusdreef 2, C4-67
L.D. Schinkel, van
Leiden 2333 ZA
The Netherlands

Wetenschappelijk

LUMC, Albinusdreef 2, C4-67
L.D. Schinkel, van
Leiden 2333 ZA
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2011
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	10-05-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2758
NTR-old	NTR2897
Ander register	METC LUMC : P10.188
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A