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Myocardial metabolic flexibility and myocardial function in patients with complicated type 2 diabetes

Submission date	Recruitment status	[_] Prospectively registered
09/03/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
P05.195

Study information

Scientific Title
Myocardial metabolic flexibility and myocardial function in patients with complicated type 2 diabetes: a prospective intervention study

Study objectives
To assess the effect of a short term very low calorie diet on myocardial triglyceride content and myocardial function in patients with complicated type 2 diabetes mellitus

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Leiden University Medical Centre, approved on 4th August 2008, reference: P05.195/SH

Study design
Prospective intervention study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
Two magnetic resonance imaging (MRI)-scans will be performed in all patients. One baseline MRI-scan will be performed while patients have used their regular diet. A second MRI-scan after a 3-day very low calorie diet (450 kcal/day) (VLCD). During the VLCD the glucose lowering medication is adjusted to prevent hypoglycemia.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Myocardial triglcyeride content measured using proton MR spectroscopy
2. Cardiac function-measured by MRI

Measured at baseline and at day 4

Key secondary outcome(s))
1. Plasma free fatty acids-blood tests
2. Plasma glucose-blood tests
3. Waist fat

Measured at baseline and at day 4

Completion date
01/01/2011

Eligibility

Key inclusion criteria
Patients with complicated type 2 diabetes mellitus, both men and women, age >18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Myocardial infarction
2. Congenital cardiac disease
3. Kidney failure
4. Pregnancy or lactation
5. Contra-indications for magnetic resonance imaging (MRI)

Date of first enrolment
10/02/2009

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Leids Universitair Medisch Centrum
Leiden
Netherlands
2333 ZA

Sponsor information

Organisation
Leiden University Medical Center (Netherlands)

ROR
https://ror.org/05xvt9f17

Funder(s)

Funder type
Government

Funder Name
Center for Translational Molecular Medicine (Netherlands) [project PREDICCt (grant 01C-104)]

Funder Name
The Netherlands Heart Foundation (Netherlands)

Funder Name
Dutch Diabetes Research Foundation (Netherlands)

Alternative Name(s)
Dutch Diabetes Research Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Netherlands

Funder Name
Dutch Kidney Foundation (Netherlands)

Alternative Name(s)
Dutch Kidney Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
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	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes