

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

Submission date
09/03/2011

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/03/2011

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/01/2014

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

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 measure

1. Myocardial triglyceride content measured using proton MR spectroscopy
2. Cardiac function-measured by MRI

Measured at baseline and at day 4

Secondary outcome measures

1. Plasma free fatty acids-blood tests
2. Plasma glucose-blood tests
3. Waist fat

Measured at baseline and at day 4

Overall study start date

10/02/2009

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

17

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)

Sponsor details

Leiden University Medical Center

c/o Prof. J.W.A. Smit

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Leiden

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Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Government

Funder Name

Center for Translational Molecular Medicine (Netherlands) [project PREDICt (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

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	01/07/2014		Yes	No