ISRCTN91251359 https://doi.org/10.1186/ISRCTN91251359

The use of magnetic resonance in non-invasive pancreatic beta-cell imaging: the relation between pancreatic triglyceride accumulation and beta-cell function in human (pre)diabetes

Submission date 08/06/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/08/2007	**Overall study status** Completed	
Last Edited 30/08/2007	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2006/219 sub1

Study information

Scientific Title

Study objectives
Pancreatic triglyceride accumulation, measured by magnetic resonance spectroscopy, is related to beta-cell function in subjects with Impaired Glucose Tolerance and/or Impaired Fasting Glucose.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee VU University Medical Center 18-12-2006 (ref: 2006/219)

Study design
Observational study.

Primary study design
Observational

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Subjects with impaired glucose tolerance and/or impaired fasting glucose

Interventions
The following will be performed in each subject:
1. A modified euglycaemic hyperglycaemic clamp with arginine stimulation (After an euglycaemic clamp [120 minutes, 5 mmol/L], there is an hour rest period followed by a hyperglycaemic clamp [110 minutes, 15 mmol/L with 5 grams arginine stimulation])
2. Magnetic Resonance Imaging (MRI) of the abdominal fat compartments
3. Proton Magnetic Resonance Spectroscopy (1H-MRS)

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
1. Triglyceride content of the human pancreas in vivo assessed using non-invasive 1H-MRS
2. Relation between pancreatic triglyceride accumulation and beta-cell function
3. Relation between triglyceride accumulation in the pancreas and other fat compartments within the abdomen

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2007

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Male and female subjects (aged 35-70 years)
2. Impaired Fasting Glucose (IFG; plasma glucose > = 6.1 and < 7.0 mmol/l) and/or
3. IFG (plasma glucose >= 5.6 and < 7.0 mmol/l) and a family history of Diabetes Mellitus type two (DM2; i.e. first and second degree [i.e. grandparents] relatives) and/or
4. Impaired Glucose Tolerance (IGT; 2-hour plasma glucose during 75 g Oral Glucose Tolerance Test [OGTT] 7.8-11.1 mmol/l)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Known diabetes
2. History or present liver, exocrine pancreatic or renal disease
3. Drug-/alcohol abuse
4. Acute cardiovascular disease <3 months prior to screening
5. Malignant disease
6. Claustrophobia and metal implants or pacemakers (MRI)
7. Lack of capacity to understand the aim of the research
8. Use of the following:
8.1. Glucocorticoids
8.2. Cytostatic drugs

8.3. Thiazolidinediones
8.4. Metformin
8.5. Oral contraceptives
8.6. Fibrates
8.7. Anti epileptic drugs
8.8. Centrally acting drugs for neurologic and/or psychiatric indications

Date of first enrolment
01/04/2007

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
VU University Medical Center, Diabetes Center (The Netherlands)

Sponsor details
c/o Dr M Diamant
VU University Medical Center
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Sponsor type
University/education

Website
http://www.vumc.nl/english/

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme B.V. Protocol number: P 2129 V1 (International)

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