# 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	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 30/08/2007	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 30/08/2007	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

## 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

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:

 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])
 Magnetic Resonance Imaging (MRI) of the abdominal fat compartments
 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

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 Deparment of Endocrinology / Diabetes Center De Boelelaan 1117 Amsterdam Netherlands 1081 HV

**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