Adipose Tissue Imaging in Patients with Type 2 Diabetes, Pilot Study

Published: 28-07-2014
Last updated: 24-04-2024

Pilot study to test the feasibility of measuring glucose uptake in adipose tissue under hyperinsulinemic hypo- ande euglycaemic conditions to quantify the effect of hypoglycaemia on metabolic activity of adipose tissue (VAT, SAT and GFAT) in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON40449

Source
ToetsingOnline

Brief title
AT imaging in T2D, pilot

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adipose tissue, F18-FDG PET/CT, Type 2 diabetes

Outcome measures

Primary outcome

FDG uptake in visceral, subcutaneous abdominal, and gluteofemoral adipose

tissue.

Secondary outcome

Not applicable.

Study description

Background summary

The metabolic function of different white adipose tissue depots in the body and its role in the development of type 2 diabetes (T2D) remains unclear. Several studies have used fluor-18 fluorodeoxyglucose positron emission tomography with computed tomography (FDG PET/CT) to image the metabolic activity of different adipose tissues in lean and obese healthy subjects and in patients with T2D with or without euglycaemic hyperinsulinemic clamping, describing differences in metabolic activity of visceral adipose tissue (VAT), subcutaneous adipose tissue (SAT) and gluteal-femoral adipose tissue (GFAT). Recently, FDG PET/CT showed high glucose uptake in VAT and SAT under unintentional hypoglycaemic conditions in a non-diabetic patient. Evaluation of potential differences in FDG uptake in white adipose tissue between healthy volunteers and T2D patients and between VAT, SAT and GFAT in these subjects under hyperinsulinemic hypoglycaemic conditions would be of great value in further exploring the pathogenesis of insulin resistance in T2D.

Study objective

Pilot study to test the feasibility of measuring glucose uptake in adipose tissue under hyperinsulinemic hypo- ande euglycaemic conditions to quantify the effect of hypoglycaemia on metabolic activity of adipose tissue (VAT, SAT and GFAT) in patients with T2D and healthy subjects by FDG PET/CT imaging, and compare it with metabolic activity at euglycemia.

Study design

Pilot feasibility study.

Intervention

FDG PET/CT under hyperinsulinemic eu- or hypoglycemic clamp conditions.

Study burden and risks

Per subject one FDG PET/CT scan during a clamping procedure. The clamping procedure will be performed under continuous supervision by an experienced physician. Low radiation burden, comparable with the background radiation of a person in the Netherlands during 3 years.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age>= 18 years
BMI 27-40
For healthy volunteers: Fasting blood glucose< 6.1 mmol/l, HbA1c< 42 mmol/mol (6%)
For patients with T2D: Clinical overt T2D, on a glucose-lowering diet or on oral glucose-lowering medication, stable and under control for minimal 2 years, HbA1c< 75 mmol/mol (9%)

Exclusion criteria

Renal dysfunction with MDRD< 60
Overt symptomatic neuropathy or proliferative retinopathy
A history of cardiovascular disease complications (myocardial infarction, stroke, peripheral artery disease)
Pregnancy or lactating
Receiving subcutaneous insulin
Incapability to provide informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	15

Type:	Actual

Ethics review

Approved WMO Date:	28-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-12-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44098.091.13