the Prevalence of Familial Partial Lipodystrophy in patients with extreme insulin-resistant type 2 Diabetes

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Ethical review	Approved WMO
Status	Pending
Health condition type	Metabolic and nutritional disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON32201

Source
ToetsingOnline

Brief title
FPLD

Condition

- Metabolic and nutritional disorders congenital
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
abnormal distribution of subcutanous fat, lipodystrophy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: anthropometric measurments, diabetes, insulin resistant, lipodystrophy

Outcome measures

Primary outcome

Skinfold measurement compared to the general population

Clinical characteristics of lipodystrophy

Secondary outcome

Cardiovascular risk profile

IMT measurements

Genetic analysis when a specific disease is suspec

Study description

Background summary

Familial partial lipodystrophy (FPLD) is an inherited disease that is characterized by an abnormal distribution of subcutaneous fat. As a result these patients have metabolic abnormalities including; insulin resistance with type 2 diabetes, acanthosis nigricans, dyslipidemia predominantly consisting of hypertriglyceridemia (associated with the onset of pancreatitis), liver steatosis and hypertension. Women are usually hirsute, often associated with the presence of polycystic ovarian syndrome (PCOS). The majority of these symptoms may to some extent also be present in patients with the metabolic syndrome. Since the prevalence of metabolic syndrome by far outweighs that of lipodystrophy, the diagnosis of this rare disorder may often be discarded as being metabolic syndrome.

Study objective

Since the first description of FPLD it is becoming increasingly evident that lipodystrophy is often misdiagnosed as diabetes with extreme insulin resistance. With this project, we want to find out the prevalence of lipodystrophy in patients with severe insulin resistance.

Study design

Those patients with an extreme insuline resistance will be selected from three different hospitals for further analysis. During a one time visit, the anthropometric measurements with a skinfold caliper will be performed in a standardized fashion. The normal distribution of fat in general population is already available in the literature. These skinfold measurements will be compared to the general population.
We will also measure Intima Media Thickness (IMT) to assess the cardiovascular burden in these patients.

Study burden and risks

There are no risks involved in this project. If the patient accepts to enter the study, he/she will be invited for a one time visit for the following assessments:

Taking history
Physical examination and anthropometric measurements
Vein puncture for drawing blood
IMT measurements

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

insulin dependent type 2 DM
more than 100 units insulin usage per day
low body mass index (BMI < 27)

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22495.018.08