Determinants of insulin-induced weight gain in patients with type 2 diabetes mellitus, a prospective study on body compostion, physical activity and metabolic markers

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Therefore, the primary aim of this study is to detect an association between energy expenditure and weight gain.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON32534

Source
ToetsingOnline

Brief title
determinants of insulin-induced weight gain in type 2 diabetes mellitus

Condition

- Diabetic complications

Synonym
diabetes, diabetes mellitus type 2

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: determinants, insulin-induced weight gain, type 2 diabetes mellitus

Outcome measures

Primary outcome

The primary objective of the proposed study is to detect an association between energy expenditure and weight gain in insulin-induced weight gain in type 2 diabetes mellitus.

Secondary outcome

Furthermore, it is hypothesised that patients who suffer most from insulin-induced weight gain will have:

1) higher caloric intake

2) higher inflammatory markers

3) lower fat hormones

4) body composition: more (trunk) fat

Study description

Background summary

Insulin therapy is frequently needed to achieve adequate glycaemic control in type 2 diabetes mellitus (T2DM), but often at the expense of weight gain. Insulin-induced weight gain is obviously undesirable in an already overweight population and may negatively affect blood pressure, lipid levels, inflammatory and fibrinolytic parameters, adipocytokines and also deter further optimization of insulin therapy. It is unknown what determinants predict insulin-induced weight gain in type 2 diabetes mellitus.

The aim of this study therefore, is to assess determinants of insulin-induced weight gain in type 2 diabetes mellitus. In a retrospective and cross-sectional study (Jansen HJ et al., submitted) two extreme subgroups were identified (subjects with a weight gain above 80th percentile) and subgroup non-weight gainers (subjects with a weight gain below the 20th percentile). It was found that the gainers had less energy expenditure after initiation of insulin therapy than non-weight gainers.

Study objective

Therefore, the primary aim of this study is to detect an association between energy expenditure and weight gain.

Study design

Prospective, multi-centre design.

Study burden and risks

All the measurements (except for venapuncture) proposed in this protocol are non-invasive.

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

• Patients with type 2 diabetes mellitus who will start with insulin therapy
• Age 18-85 years
• Baseline HbA1c < 12.0%
• Written informed consent

Exclusion criteria

• Clinical evidence of psychiatric, renal, cardiovascular or liver or other diseases which may influence study results regarding glucose and weight.
• Patients with hormonal disorders which may influence weight (i.e. thyroid diseases), unless properly treated with stable hormonal levels.
• Excessive alcohol consumption (>20 g/day), and drug abuse
• Use of thiazolidinedione derivatives (TZDs)
• Pregnancy or intention to become pregnant during the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2008
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	25-11-2008
Application type:	First submission
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	NL24179.091.08