Determinants of insulin-induced weight gain in patients with type 2 diabetes mellitus, a study on liver fat content, physical activity and metabolic markers comparing weight gainers vs. non-weight gainers

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The primary objective of the proposed study is to compare intracellular lipid levels in liver with 1H-magnetic resonance spectroscopy between weight gainers and non-weight gainers after longstanding insulin treatment for type 2 diabetes mellitus.We...

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

Summary

ID

NL-OMON31007

Source
ToetsingOnline

Brief title
Weight gain and insulin therapy

Condition

- Diabetic complications

Synonym
type 2 diabetes mellitus

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: insulin therapy, Type 2 diabetes mellitus, Weight gain

Outcome measures

Primary outcome

see objective of the study

Secondary outcome

see objective of the study

Study description

Background summary

Insulin therapy is frequently needed to achieve adequate glycaemic control in type 2 diabetes mellitus, but often at the expense of weight gain. However, this weight gain shows large inter-individual differences. It is not exactly known what kind of mechanisms play a role in these inter-individual differences. Potential consequences for insulin-induced weight gain may be change in body-composition (i.e. fat distribution), physical activity, diet and inflammatory activity. With respect to change in fat distribution, insulin inhibitis lipolysis and stimulates lipogenesis in adipose tissue and lowers serum free fatty acids, which might reduce liver fat content. It also stimulates fatty acids and VLDL synthesis in the liver. It is unclear whether fat content in the liver is a cause or rather a consequence of hyperinsulinemia. Juurinen et al. (Am J Physiol Endocrinol Metab, 2007) examined the role of insulin therapy on liver fat content and hepatic insulin sensitivity in obese patients with poorly controlled type 2 diabetes. After 7 months of insulin therapy there appeared to be an improvement of hepatic insulin sensitivity and slightly but significantly reduction of liver fat.
It is not known whether liver fat content changes in patients with type 2 diabetes comparing weight gainers and non-weight gainers after longstanding insulin therapy. Furthermore, it is not known whether gainers differ in their

fat composition, physical activity and dietary habits compared to non-gainers. These questions will be tested in this study.

Study objective

The primary objective of the proposed study is to compare intracellular lipid levels in liver with 1H-magnetic resonance spectroscopy between weight gainers and non-weight gainers after longstanding insulin treatment for type 2 diabetes mellitus.

We hypothesised that weight gainers will have higher intracellular lipid levels than the non-weight gainers.

The secondary objectives of the proposed study will be to compare body-composition, physical activity, diet and inflammotory markers between weight gainers and non-weight gainers after longstanding insulin treatment for type 2 diabetes mellitus.

It is hypothesised that weight gainers will have:
1) more trunk fat
2) lower physical activity
3) higher caloric intake
4) higher inflammatory markers
5) lower fat hormones

Study design

This will be a cross-sectional study recruiting patients who were formerly studied for weight gain after starting with insulin therapy (Jansen et al., article submitted).

Study burden and risks

There are no extra risks regarding the investigation, except for DEXA-scan. Patients receive by DEXA 12 microSv.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
Nederland

Scientific
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

· Type 2 diabetes mellitus
· Premixed insulin
· Age 20-85 years
· HbA1c < 8.5%
· Increase in body weight defined as a weight increase > 6 kg in any given period of 12 months (> 0.5 kg/months over 12 months) over a time period of 12-36 months after start of insulin therapy
· Stable body weight
· Current insulin dose >0.4 IU/kg - < 1.2 IU/kg
· Written informed consent

Exclusion criteria

· Clinical evidence of cardiovascular or liver or other disease
· Treatment with drugs that may alter glucose tolerance, abnormal serum creatinine, macroalbuminuria, proliferative retinopathy, excessive alcohol consumption (>20 g/day), and drug abuse
· Use of thiazolidinedione derivatives (TZDs)
· Patients with pacemakers, ICD*s, implants of metal (prosthesis, (cochlear) ear implants) and patients who experience claustrophobia

· Pregnancy or intention to become pregnant during the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

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	NL19246.091.07