The role of RBP4 in human glucose metabolism

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To study the differences in adipose tissue, liver and circulating levels of RBP4 in lean versus obese, diabetic and obese insulin, non-diabetic subjects in relation to glucose fluxes and hepatic triglyceride content

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON39627

Source
ToetsingOnline

Brief title
RBP4 and glucose metabolism

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
glucose intolerance, Insulin resistance

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Metabole fonds

Intervention

Keyword: Insulin sensitivity, Obesity, RBP4

Outcome measures

Primary outcome

Circulating and tissue levels of RBP4, in relation to: endogenous glucose production; hepatic, peripheral and adipose tissue insulin sensitivity; hepatic triglyceride content

Secondary outcome

Correlation levels of RBP4 with hepatic enzymes involved in gluconeogenesis

Study description

Background summary

Retinol binding protein (RBP4) is a small 21 kDa protein that belongs to the family of lipocalins. RBP4 is primarily synthesized in hepatocytes, but other sites of synthesis are known including adipocytes. Recently RBP4 has been proposed as an adipokine that is involved in obesity-induced insulin resistance. We aim to assess whether serum and tissue RBP4 levels are elevated in these metabolically altered states and whether these levels are correlated with glucose fluxes. This gives more insight in the pathophysiological role of RBP4 in glucose intolerance and diabetes in obesity and will shed light on whether it would be useful to develop agents that decrease RBP4 expression.

Study objective

To study the differences in adipose tissue, liver and circulating levels of RBP4 in lean versus obese, diabetic and obese insulin, non-diabetic subjects in relation to glucose fluxes and hepatic triglyceride content

Study design

Observational study

Study burden and risks

The hyperinsulinemic clamp and the use of stable isotopes are safe. Hypoglycemia during the clamp will be avoided by measuring plasma glucose regularly. The risk of bleeding from the liver and intra abdominal fat biopsies will be reduced by checking local hemostasis during and twice after the biopsy. If needed electrical coagulation will be performed. MRS does not pose a risk.

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

Female; BMI > 35 kg/m2; Age between 26 and 50 years; Established T2DM

Exclusion criteria

Primary lipid disorder or secondary lipid disorder treated with fibrates; T2DM treated with thiazolidinediones, DPP4-inhibitors or GLP1-analogues; Any medical condition except for glucose intolerance, hypertension and secondary dyslipidemia; Bleeding disorder; Untreated primary hypothyroidism; Contra-indications for MR scanning

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	18-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2013
Application type:	Amendment
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	NL42240.018.12