The effect of a bile acid sequestrant on bile acid- and glucose metabolism in patients with impaired glucose tolerance.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24802

Source
Nationaal Trial Register

Brief title
ABACADABRA study

Health condition

diabetes mellitus type 2, bile acid metabolism

Sponsors and support

Primary sponsor: No
Source(s) of monetary or material Support: fund

Intervention

Outcome measures

Primary outcome

The primary endpoints are changes in bile acid composition.

Secondary outcome

Secondary endpoints are changes in hepatic and peripheral insulin resistance (assessed by hyperinsulinemic euglycemic clamp at baseline and after 12 weeks), metabolic parameters (lipid profile, glycemic control) as well as changes in faecal microbiota, glucose and lipid content (assessed by analysing faeces samples). Finally, muscle and adipose tissue samples will be obtained to assess D2 mRNA and activity and phosphorylation status of the insulin signalling cascade.

Study description

Background summary

Objective:
To investigate the effects of colesevelam (bile acid sequestrant) on bile acid composition, insulin resistance, glucose metabolism and composition of faecal flora in patients with an impaired glucose tolerance or newly diagnosed type 2 diabetes.

Study design:
Double blind randomized controlled single center trial.

Study Population:
Male obese subjects with an impaired glucose tolerance or newly diagnosed type 2 diabetes mellitus (fasting glucose > 6,0 mmol/l).

Treatment:
Patients will be randomised to either colesevelam treatment or placebo treatment for a period of 12 weeks.

Outcome measures:
The primary endpoints are changes in bile acid composition. Secondary endpoints are changes in hepatic and peripheral insulin resistance (assessed by hyperinsulinemic euglycemic clamp at baseline and after 12 weeks), metabolic parameters (lipid profile, glycemic control) as well as changes in faecal microbiota, glucose and lipid content (assessed by analysing faeces samples). Finally, muscle and adipose tissue samples will be obtained to assess D2 mRNA and activity and phosphorylation status of the insulin signalling cascade.

Powercalculation:
It is estimated that a total of 24 patients (12 patients per treatment arm) are needed to achieve statistical significant outcomes.

Study objective

Colesevelam is a bile sequestrant that not only improves lipid parameters, but also improves glycemic control. The workingsmechanismen of colesevelam is yet unknown. We hypothezize that treatment of obese insulin resistant subjects with colesevelam increases hepatic insulin

sensitivity. In this study we want to investigate effect of colesevelam on bile acid composition, insulin resistance and glucose metabolism in patients with an impaired glucose tolerance or newly diagnosed type 2 diabetes.

Study design

Bile acid metabolism will be measured before and after 12 weeks, using stable isotopes. Additionally insulin sensitivity is determined before and after 12 weeks by a two-step hyperinsulinemic euglycemic clamp using stable isotopes. Changes in liopid parameters/metabolic control and faecal flora composition will be determined before as well as after 4, 8 and 12 weeks after start of the trial.

Intervention

Patients will be randomised to either colesevelam treatment or placebo treatment for a period of 12 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male obese subjects with an impaired glucose tolerance or newly diagnosed type 2 diabetes mellitus (fasting glucose > 6,0 mmol/l);

2. Age 18-55 yr;

3. BMI>30 kg/m2.

Exclusion criteria

1. Medication known to interfere with glucose metabolism or bowel flora composition;

2. Severe hypertriglyceridemia or any other lipid metabolism disorder;

3. Intensive sports (> three times weekly).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2009
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-04-2009
Application type:	First submission

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
NTR-new	NL1647
NTR-old	NTR1745
Other	EudraCT : 2009-011972-31
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A