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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24802

Bron
Nationaal Trial Register

Verkorte titel
ABACADABRA study

Aandoening

diabetes mellitus type 2, bile acid metabolism

Ondersteuning

Primaire sponsor: No
Overige ondersteuning: fund

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoints are changes in bile acid composition.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2009
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-04-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1647
NTR-old	NTR1745
Ander register	EudraCT : 2009-011972-31
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A