FATLOSE 2 trial (Fecal Administration To LOSE insulin resistance).

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Recent research shows that obesity is associated with changed bowel flora composition with a relative abundance of the two dominant bacterial divisions, the Bacteroidetes and the Firmicutes. Interestingly, this specific bacteria associated condition...

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

Samenvatting

ID

NL-OMON21653

Bron
Nationaal Trial Register

Verkorte titel
FATLOSE2

Aandoening

insulin resistance, obesity, gut microbiota, SCFA

Ondersteuning

Overige ondersteuning: Academic Medical Center (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is changes in weight in relation to fecal flora composition and short chain fatty acid metabolism in fecal samples after 3, 6, 12 and 18 weeks.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective:

To investigate whether single vs multiple doses of fecal therapy by infusion of allogenic (lean donor feces in the bowel) or autologous (own feces) have differential effect on longterm reduction of insulin resistance, postprandrial dyslipidemia and short chain free fatty acid metabolism.

Study design:

Double blind randomized controlled single center trial.

Study Population:

Male obese patients with metabolic syndrome.

Treatment:

Patients will be randomised to one of the three treatment arms: Single (baseline) or multiple (at baseline and after 6 weeks) allogenic feces (infusion of lean donor feces by duodenal tube) or single autologous (own) feces at baseline.

Outcome measures:

The primary endpoint changes in fecal flora composition and shortchain fatty acid metabolism in fecal samples after 3, 6, 12 and 18 weeks. Secondary endpoints are changes in insulin resistance/fatty acid metabolism (assessed by hyperinsulinemic normoglycemic clamp and stable isotope glucose) and postprandrial lipidmetabolism (mixed meal test) at baseline and after 6 and 18 weeks. Finally, changes in gutregulatory hormones in plasma (leptin, adiponectin and GLP-1) will be assessed.

Sample Size:

It is estimated that a total of 45 patients (15 MS patients per treatment arm) and 30 healthy lean volunteers are need.

Doel van het onderzoek

Recent research shows that obesity is associated with changed bowel flora composition with a relative abundance of the two dominant bacterial divisions, the Bacteroidetes and the Firmicutes. Interestingly, this specific bacteria associated condition is transmissible: colonization of obese mice with an ‘leanmicrobiota’ results in a significantly greater decrease in total body fat (-30%) than colonization with a ‘obese microbiota’ (+5%). In addition, Bacteroidetes species are decreased and Firmicutes increased in feces of obese people compared to lean people . We recently finished the FATLOSE trial, in which we studied the therapeutic effect of donor feces infusion from screened volunteers after 6 weeks on insulin resistance (hyperisulinemic clamp with stable isotopes) in male patients with metabolic syndrome. We found significant reduction in both periferal and hepatic insulin resistance implicating substantial effects of whole body glucose metabolism. Moreover, we found significant reductions in fasting lipidprofiles after allogenic fecal therapy, which are in line with previously published data suggesting a direct effect between duodenal lipid uptake and glucose production orchestrated by gutmicrobiota driven brain-gut axis. The efficacy of fecal therapy is explained by enhanced production of specific short chain free fatty acid butyrate produced by the infused lean donor feces, which probably restores normal fecal physiology by implantation of missing lean-figure flora components.

Onderzoeksopzet

Baseline, 3, 6, 12 and 18 weeks.

Onderzoeksproduct en/of interventie

Patients will be randomised to one of the three treatment arms:

Single (baseline) or multiple (at baseline and after 6 weeks) allogenic feces (infusion of lean donor feces by duodenal tube) or single autologous (own) feces at baseline and after 6 weeks.

Contactpersonen

Publiek

PO Box 22660
A. Vrieze
Academic Medical Center, room F4-256
Amsterdam 1100 DD

The Netherlands
+31 (0)20 5665983

Wetenschappelijk

PO Box 22660
A. Vrieze
Academic Medical Center, room F4-256
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5665983

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male obese subjects with metabolic syndrome (n=45);

2. 21 to 69 years-old;

3. Body mass index (BMI) 30 to 43 kg/m2);

4. At least 3 out of 5 NCEP metabolic syndrome criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Cardiovascular event (MI or pacemaker implantation);

2. Use of medication including PPI and antibiotics;

3. (Expected) prolonged compromised immunity (due to recent cytotoxic chemotherapy or HIV infection with a CD4 count < 240).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	45
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-01-2011
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	NL2580

Register	ID
NTR-old	NTR2705
Ander register	CCMO : 35474
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A