

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, postprandial 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 postprandial 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 needed.

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 (hyperinsulinemic clamp with stable isotopes) in male patients with metabolic syndrome. We found significant reduction in both peripheral and hepatic insulin resistance implicating substantial effects of whole body glucose metabolism. Moreover, we found significant reductions in fasting lipid profiles 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

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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
Blinding:	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

NTR-old

Ander register

ISRCTN

ID

NTR2705

CCMO : 35474

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A