Effect of Fecal microbiotA Transplantation combined with MEditerranean Diet on insulin sensitivity in subjects with metabolic syndrome

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To study if a Mediterranean diet (MD) followed by lean donor fecal microbiota transplantation (FMT) has synergistic superior beneficial effects on peripheral insulin sensitivity and (small) intestinal microbiota composition as compared to...

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

Samenvatting

ID

NL-OMON23913

Bron
NTR

Verkorte titel
FATMED trial

Aandoening

metabolic syndrome
insulin resistance
microbiota
mediterranean diet

Ondersteuning

Primaire sponsor: ZONMW
Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Effect of mediterranean diet followed by lean donor FMT versus mediterranean diet followed by autologous FMT on intestinal microbiota composition at 0,3,6, and 12 weeks .

Toelichting onderzoek

Achtergrond van het onderzoek

Previous research has shown that faecal microbiota transplantation of lean healthy donors improves insulin sensitivity (Vrieze et al., 2012) and recent data have suggested that engraftment of beneficial lean donor bacterial differs between metabolic syndrome subjects (Li-Nieuwdorp, Science 2016). Since diet is thought to be of pivotal importance in stabilizing gutmicrobiota composition (David et al., 2014; De Filippis et al., 2015) we hypothesize that prescription of a healthy (Mediterranean) diet before lean donor fecal transplantation will allow enhanced engraftment of beneficial bacteria in the intestine of metabolic syndrome subject and will have a synergistic beneficial effect on peripheral insulin sensitivity.

Doel van het onderzoek

To study if a Mediterranean diet (MD) followed by lean donor fecal microbiota transplantation (FMT) has synergistic superior beneficial effects on peripheral insulin sensitivity and (small) intestinal microbiota composition as compared to prescription of Mediterranean diet (MD) followed by autologous (own) FMT in male subjects with metabolic syndrome.

Onderzoeksopzet

0.6 weeks

Onderzoeksproduct en/of interventie

fecal transplantation (allogeneic/lean donor or autologous) on top of mediterranean diet

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

-Male obese subjects with metabolic syndrome

-21 to 65 years-old

-body mass index (BMI) 30 to 43 kg/m2)

-3 out of 5 NCEP metabolic syndrome criteria (fasting plasma glucose ¡Ý 6.1 mmol/l, triglycerides ¡Ý 1.7 mmol/l, waist-circumference > 102 cm, HDL-cholesterol < 1.04 mmol/l, blood pressure ¡Ý 130/85 mmHg)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Use of any medication, including proton pomp inhibitors and antibiotics in the past three months

- Cholecystectomy

- A history of cardiovascular event (MI or pacemaker implantation)

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

- Unmotivated or not able to adhere to a specific diet.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2016
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2016
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	NL5828
NTR-old	NTR5983
Ander register	: METC 2016_117

Resultaten