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

No registrations found.

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

Summary

ID

NL-OMON23913

Source
NTR

Brief title
FATMED trial

Health condition

metabolic syndrome
insulin resistance
microbiota
mediterranean diet

Sponsors and support

Primary sponsor: ZONMW
Source(s) of monetary or material Support: ZONMW

Intervention

Outcome measures

Primary outcome

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 .

Secondary outcome

changes in insulin sensitivity (hyperinsulinemic clamp) at baseline and after 6 weeks

Secundary objective:

- Changes in postprandial plasma glucose and incretins (mixed meal test) at baseline and 6 weeks

- Changes in subcutaneous adipose tissue inflammation (Subcutaneous adipose tissue biopsy) at baseline and 6 weeks

- Changes in 24h fecal and urine metabolites (feces and urine samples)

Study description

Background summary

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.

Study objective

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.

Study design

0.6 weeks

Intervention

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

Contacts

Public
AFDELING INWENDIGE GENEESKUNDE AMC
MEIBERGDREEF 9, KAMER F4.159.2
M. Nieuwdorp
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666612
Scientific
AFDELING INWENDIGE GENEESKUNDE AMC
MEIBERGDREEF 9, KAMER F4.159.2
M. Nieuwdorp
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666612

Eligibility criteria

Inclusion criteria

-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)

Exclusion criteria

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2016
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-07-2016
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	NL5828
NTR-old	NTR5983
Other	: METC 2016_117

Study results