FATLOSE trial: Fecal Administration To LOSE weight.

No registrations found.

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

Summary

ID

NL-OMON23407

Source
Nationaal Trial Register

Brief title
FATLOSE trial

Health condition

metabolic syndrome, fecal therapy

Sponsors and support

Primary sponsor: Academic Medical Centre
PO Box 22660
1100 DD Amsterdam
tel: +31-20-5669111
Source(s) of monetary or material Support: Academic Medical Centre
PO Box 22660
1100 DD Amsterdam
tel: +31-20-5669111

Intervention

Outcome measures

Primary outcome

1. Fecal flora composition;

2. Weight.

Secondary outcome

1. Insulin resistance;

2. Biochemical parameters;

3. Inflammatory parameters;

4. Gut epithelium (duodenal and jejunal mucosal biopsies).

Study description

Background summary

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 than colonization with a ‘obese microbiota. In addition, Bacteroidetes species are decreased and Firmicutes increased in feces of obese people compared to lean people. Moreover weight correlated with percentage loss of body weight in obese subjects. Changing fecal flora composition in overweight MS patients might therefore be total novel and effective prevention of the rapid increase patients with type 2 diabetes, that is needed so urgently. This trial is performed which infusion of lean donor feces through a duodenal tube, compared with autologic (patients own feces) transplantation.
Endpoints are changes in faecal flora, weight, insulin resistance and systhemic/biochemical parameters.
Folluw up is 12 weeks

Study objective

Hypothesis: infusion of lean donor feces in obese subjects is effective on weight reduction, systemic inflammatory pathways and insulin resistance.

Study design

1. Baseline;

2. 2days;

3. 2 weeks;

4. 6 weeks;

5. 12 weeks.

Intervention

1. Arm 1: allogenic fecal therapy
(donor feces from lean volunteer);

2. Arm 2: autologic fecal therapy
(patients' own feces).

Contacts

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Eligibility criteria

Inclusion criteria

1. Male obese subjects with metabolic syndrome (at least 3 out of 5 NCEP metabolic syndrome criteria);

2. 21-65 yr.

Exclusion criteria

1. Cardiovascular event;

2. Diabetic kidney failure;

3. Prolonged compromised immunity;

4. Antidiabetic medicine;

5. Lipid lowering medicine.

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):	01-01-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-04-2009
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	NL1675
NTR-old	NTR1776
Other	CCMO : 17378
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A