Effect of Fecal transplant harvested from Bariatric surgery subjects on Lipid and Glucose metabolism in subjects with metabolic syndrome;

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To investigate whether single dosis of fecal therapy by infusion of allogeneic (post bariatric surgery donor feces in the bowel) or autologous (own feces) have differential effect on lipid-metabolism-mediated insulin resistance.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolic and nutritional disorders congenital
Study type	Interventional

Summary

ID

NL-OMON38792

Source
ToetsingOnline

Brief title
FEBALIGO study

Condition

- Metabolic and nutritional disorders congenital
- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders

Synonym
Metabolic syndrome obesity and type 2 diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bariatic surgery, Glucose metabolism, Lipid metabolism, Metabolic syndrome

Outcome measures

Primary outcome

Changes in insulin sensitivity and de novo lipogenesis as measured by hyperinsulinemic euglycemic clamp with stable isotopes at 0 and 2 weeks and by measuring energy excretion, short chain fatty acids profile and bile acid concentration in 2x 24h collected feces.

Secondary outcome

Secondary and further study parameters needed to answer the research question:
Changes in adipose tissue inflammation by subcutaneous adipose tissue biopsy (to assess phosphorylation status of the insulin signalling cascade in relation to metabolic genes (perilipin3) and to evaluate dipose tissue inflammation (macrophage counts). Inflammatory markers in serum will also be measured.

Tertiary end points:
small and large intestinal microbiota in relation to intestinal transit time (segmental SITZMARKS) at 0 and 2 weeks.

Study description

Background summary

Recent research suggests that obesity is associated with variations in bowel flora composition (Vrieze, FATLOSE-1-trial, Gastroenterology 2012) Interestingly, this seemingly bacteria-associated condition is transmissible: colonization of obese mice with a *lean microbiota* results in a significantly greater decrease in total body fat (-30%) than colonization with an *obese microbiota* (+5%). Moreover fecal transplants from lean human donors were found to improve peripheral and hepatic insulin resistance and glucose and lipid metabolism in male patients with metabolic syndrome [Vrieze et al. GE FATLOSE 1].
Bariatric surgery is an increasingly employed intervention in morbidly obese patients. Bariatric surgery (gastric bypass or GBP) has not only a weight dependent, but also a weight-independent mitigating effect on insulin resistance [Laferrère et al 2012]. A significant increase in incretin level and effect is seen after GBP that is not seen after weight loss due to calory restriction alone [Laferrère, JCEM, 2008]. This led to the hypothesis that bowel factors including bowel transit time are involved rather than abdominal fat cell factors. The intestinal microbiota might play a significant role.
Recent investigation indicates that T2D-mice have reduced insulin resistance after transplantation with microbiota from patients that have undergone GBP [Liou, Science Translational Medicine 2013].. It is our aim to investigate this principle in humans.
Our hypothesis is that intestinal microbes have a differential effect on bacterial translocation, intestinal transit time and lipid metabolism. These are interrelated and each contribute to systemic inflammatory processes (such as adipose tissue inflammation) that lead to insulin resistance.

Study objective

To investigate whether single dosis of fecal therapy by infusion of allogeneic (post bariatric surgery donor feces in the bowel) or autologous (own feces) have differential effect on lipid-metabolism-mediated insulin resistance.

Study design

Single blind randomized controlled single center trial.

Intervention

Patients will be randomised to one of the two treatment arms: single allogeneic feces (post bariatric surgery donor feces in the bowel by duodenal tube) vs.

single allogeneic feces from a pre-bariatric surgery donor.

Study burden and risks

2 gastroscopies, 2 insuline-glucose-clamps with resting energy expenditure measurement and glycerol isotope bolus infusion, 2 adipose tissue biopsies, 5 abdominal X-rays. Minimal health risks (<0.01% perforation with gastroscopy)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
Males

Meeting the criteria for metabolic syndrome (ATP-III criteria)
No relevant (confounding) comorbidity or medication use;Feces donors post-RYGB:
Males
+- 1 year after gastric bypass with significant weight loss
No relevant (confounding) comorbidity
free of transmissible diseases upon screening;Feces donors pre-RYGB:
Males
Scheduled for gastric bypass (RYGB)
No relevant (confounding) comorbidity
free of transmissible diseases upon screening

Exclusion criteria

Patients:
relevant comorbidity
additional medication use except when directly related to metabolic syndrome
antibiotic use in the last 3 months;Feces donors (pre- and post-RYGB):
relevant morbidity
medication use
PPI or antibiotic use in the last 3 months
frequent patient contact

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2013
Enrollment:	33

Type:	Actual

Ethics review

Approved WMO Date:	31-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL43964.018.13