Effects of butyrAte comPared to donor faeces transPlantation on mETabolIsm and saTiEty in patients with metabolic syndrome

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26960

Source
NTR

Brief title
APPETITE study

Health condition

insulin resistance, overweight, gutmicrobiota

Sponsors and support

Primary sponsor: AMC-uvA
Source(s) of monetary or material Support: EU FP7

Intervention

Outcome measures

Primary outcome

- Insulin sensitivity and lipolysis (2-step hyperinsulinemic euglycemic clamp)

- Hypothalamic (SPECT-scan), small intestinal (biopsy) and urinal (24h urine sample) serotonin levels in relation to satiety testing

Secondary outcome

- Faecal energy excretion and short chain fatty acid and bile acid concentration in feces

- Dietary intake (dietary lists), resting energy expenditure (calorimetry) and physical activity energy expenditure (accelerometers)

- Faecal and small intestinal gut microbiota composition (morning stool samples and biopsies)

- Intestinal permeability (faecal calprotectin levels)

- Intestinal passage time (Sitzmark capsules)

- Sympathetic tone (Nexfin)

- Inflammatory and lipid-proteomic markers (blood samples)

- Liver fat for NAFLD/NASH degree (MRI)

Study description

Background summary

In this RCT we aim to dissect whether intestinal microbiota or their product butyrate affect human (serotonin) driven satiety and insulin resistance in humans.

Study objective

Intestinal bacteria have been linked to human metabolism. Animal studies have suggested that the intestinal microbiota product butyrate itself can also affect satiety and improves insulin sensitivity. The question thus remains whether increasing intestinal levels of butyrate itself has the same metabolic effects as increasing levels of intestinal butyrate-producing bacterial strains. We therefore aim to compare the effects of oral butyrate vs donor fecal transplantation on insulin sensitivity, intestinal transit time and serotonin mediated satiety in treatment naive patients with insulin resistance.

Study design

0 and 4 weeks

Intervention

allogenic healthy (postbariatric surgery) donor feces transplantation + placebo tablets for 4 weeks VERSUS autologous fecal transplantation + sodium butyrate tablets for 4 weeks

Contacts

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Eligibility criteria

Inclusion criteria

- Caucasian male or postmenopausal female

- 50-70 years old

- BMI ≥30 kg/m2

- At least 3 out of 5 NCEP metabolic syndrome criteria: fasting plasma glucose ≥ 5.6 mmol/l, triglycerides ≥ 1.7 mmol/l, waist-circumference > 102 cm, HDL-cholesterol 1.04 mmol/l, blood pressure ≥ 130/85 mmHg

- Subjects should be able and willing to give informed consent

Exclusion criteria

-Any Medication use, including PPI and antibiotics in last 3 months

- Drug abuse

- Alcohol abuse (>3/day)

- Participation in a research protocol involving radiation exposure in the last 2 years.

- eGFR <60 ml/min

- Contraindication for MRI (claustrophobia)

- History of cardiovascular event (MI or pacemaker implantation)

- Cholecystectomy

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	24
Type:	Actual

Ethics review

Positive opinion

Date:	01-08-2014
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	NL4488
NTR-old	NTR4713
Other	: MEC 14/084

Study results