Effect of duodenal infusion of Eubacterium hallii on gene expression and postprandial glucose metabolism in males with metabolic syndrome

No registrations found.

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

Summary

ID

NL-OMON23717

Source
NTR

Brief title
EDIE trial

Health condition

metabolic syndrome
insulin resistance
gut microbiota

Sponsors and support

Primary sponsor: AMC-UVA
Source(s) of monetary or material Support: AMC-UVA

Intervention

Outcome measures

Primary outcome

The primary endpoint is effect on duodenal E. hallii levels as well as small intestinal gene expression (small intestinal biopsy) 6 hours after duodenal infusion of either E. hallii 10e9 cells in 10 ml glycerol 10% (active compound) OR 10ml of 10% glycerol alone (placebo).

Secondary outcome

Secondary endpoints are effect upon intervention

-(postprandial) glucose and metabolite during standardized mixed meal test

-changes in (postprandial) glucose excursions using continue glucose meter (Freestyle libre) in the days after intervention

-changes in E. hallii and other microbiota in fecal samples collected at baseline, 24h and week 1 and week 4 after intervention.

- effect on dietary intake (by online dietary lists).

Study description

Background summary

In this study we aim to study effect of single dose treatment with butyrate producing bacterial strain Eubacterium hallii versus placebo on small intestinal gene expression , intestinal e hallii levels, effect on (postprandial) glucose and plasma metabolites excursions as well as changes in intestinal microbiota composition and effect on dietary intake.

Study objective

In this randomised, double-blind, placebo-controlled single centre study we propose to study the effect of duodenal infusion of single E. hallii treatment (administered via duodenal tube) on small intestinal gene expression, bacterial composition and (postprandial) glucose excursions in male subjects with metabolic syndrome

Study design

see above

Intervention

Subjects will be given duodenal infusion of 10 ml E. hallii suspension with a total concentration of 10e9 cells in 10% glycerol or 10ml 10 % glycerol only

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, patients must meet all of the following criteria:

- Caucasian males

- 21 to 69 years-old

- body mass index (BMI) 25 to 43 kg/m2

- At least 3 out of 5 NCEP metabolic syndrome criteria: fasting plasma glucose ≥ 5.6 mmol/l and/or HOMA-IR ≥ 2.5, triglycerides ≥ 1.6 mmol/l, waist-circumference > 102 cm HDL-cholesterol ≤ 1.04 mmol/l, blood pressure ≥ 130/85 mmHg

Exclusion criteria

A history of cardiovascular event (myocardial infarction or pacemaker implantation), smoking, cholecystectomy, use of medication including proton pump inhibitors (PPI as this influences intestinal microbiota composition see ref 3), oral anticoagulants and/or oral antibiotics in the past three months, (expected) prolonged compromised immunity (e.g. due to recent cytotoxic chemotherapy or HIV-infection with a CD4 count < 240). Subjects are also excluded if they have experienced excessive weightloss of >10% in the last months or have overt untreated GI disease/abnormal bowelhabits; moreover, if their levels of plasma

aspartate aminotransferase and alanine aminotransferase are 2.5 times or more the upper limit of the normal range; if they have a history of heavy alcohol use (>12 to 15 g of alcohol per day, or >12 oz of beer, 5 oz of wine, or 1.5 oz of distilled spirits); or overt Dm2.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-11-2017
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	NL6630
NTR-old	NTR6807
Other	: MEC 2017/158

Study results