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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23717

Bron
NTR

Verkorte titel
EDIE trial

Aandoening

metabolic syndrome
insulin resistance
gut microbiota

Ondersteuning

Primaire sponsor: AMC-UVA
Overige ondersteuning: AMC-UVA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

see above

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2017
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6630
NTR-old	NTR6807
Ander register	: MEC 2017/158

Resultaten