Effect of oral Eubacterium Hallii on postprandial glucose metabolism in males with type 2 diabetes treated with metformin

Gepubliceerd: 09-07-2018 Laatst bijgewerkt: 18-08-2022

After a runic phase of 2 weeks, we will study whether cotreatment of oral E hallii once daily given for 2 weeks on top of stable metformin dosage improves (postprandial) glycemic control in DM2 subjects compared to once daily glycerol placebo with...

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

Samenvatting

ID

NL-OMON28536

Bron
Nationaal Trial Register

Verkorte titel
EDM2 trial

Aandoening

type 2 diabetes
metformin

Ondersteuning

Primaire sponsor: AMC-UvA
Overige ondersteuning: AMC-UvA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is the effect of E. hallii versus placebo on (postprandial) glucose excursions as determined by a wearable CGM glucose sensor during 14 days after the start of the intervention

Toelichting onderzoek

Achtergrond van het onderzoek

With this study we aim to study if the intestinal lactate usually generated by oral metformin treatment can be used as substrate by E haliii in order to produce more butyrate and thus improve postprandial glucose handling and insulin sensitivity in patients with type 2 diabetes on stable oral metformin dosages.

Doel van het onderzoek

After a runic phase of 2 weeks, we will study whether cotreatment of oral E hallii once daily given for 2 weeks on top of stable metformin dosage improves (postprandial) glycemic control in DM2 subjects compared to once daily glycerol placebo with metformine

Onderzoeksopzet

- 2 till 0 weeks (run in phase) and 0-2 weeks (active Ehallii or placebo treatment).

Onderzoeksproduct en/of interventie

- oral 10 ml active E. hallii suspension with a total concentration of 10e9 cells in 10% glycerol for 2 weeks on top of stable dosis of metformin

- oral 10ml glycerol 10 % (placebo) for two weeks on top of stable dosis of metformin

Contactpersonen

Publiek

Department of Vascular Medicine, AMC
Erik Stroes

Amsterdam
The Netherlands
+31 (0)20 5665978

Wetenschappelijk

Department of Vascular Medicine, AMC
Erik Stroes
Amsterdam
The Netherlands
+31 (0)20 5665978

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Caucasian males

• 21 to 69 years-old

• diagnosed with type 2 diabetes using oral metformin on a stable dose (i.e. no changes in the last three months)

• no other medication use

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Smoking

• Alcohol abuse (>12 to 15 g of alcohol per day)

• History of cardiovascular event (myocardial infarction or pacemaker implantation)

• Cholecystectomy

• Use of medication other than metformin, including insulin, proton pump inhibitors (PPI as this influences intestinal microbiota composition)6, 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)

• Excessive weight loss of >10% in the last months or have overt untreated GI disease/ abnormal bowel habits.

• Levels of plasma aspartate aminotransferase and alanine aminotransferase 2.5 times or more the upper limit of the normal range

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	31-01-2019
Aantal proefpersonen:	24
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-07-2018
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	NL7121
NTR-old	NTR7326
Ander register	: METC 2018/112

Resultaten