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

No registrations found.

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

Summary

ID

NL-OMON28536

Source
NTR

Brief title
EDM2 trial

Health condition

type 2 diabetes
metformin

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 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

Secondary outcome

Secondary endpoints are changes in (postprandial) plasma metabolites and glucose/lipids upon standardized meal in relation to changes of E. hallii and other microbiota as well as SCFA in plasma/fecal samples. Also Daily dietary intake will be monitored during the course of the study. Also ambulatory blood pressure measurements during 24 hours will be done before and after treatment.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

- 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

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2019
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-07-2018
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	NL7121
NTR-old	NTR7326
Other	: METC 2018/112

Study results