Dosefinding trial studying effect of 4 weeks Intervention on safety and efficacy in males with Metabolic syndrome with oral Eubacterium hallii

No registrations found.

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

Summary

ID

NL-OMON22563

Source
Nationaal Trial Register

Brief title
DIME study

Health condition

metabolic syndrome, obesity, insulin resistance, NAFLD

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: investigator initiated

Intervention

Outcome measures

Primary outcome

- Safety (plasma biochemistry eg hepatic /inflammatory/cholesterol markers) and

increase in fecal E. hallii levels upon increasing dosages of daily oral Ehallii treatment

- Insulin sensitivity as assessed by hyperinsulinemic clamp using stable isotope infusion) at baseline and 4 weeks upon increasing dosages of daily oral Ehallii treatment

Secondary outcome

- Effect on daily dietary intake and bowel habits (monitored using standardized questionnaires)

- Intestinal fecal microbiota composition (including fecal E. hallii) upon increasing dosages of daily oral Ehallii treatment

- Effects on bile acid metabolism in 24h feces

- Liver fat content (hepatic MRI) upon increasing dosages of daily oral Ehallii treatment

- Persistance of fecal E.hallii after cessation of 4 weeks treatment by collecting fecal samples at 5 and 6 weeks.

Study description

Background summary

Based on our animal data, we will investigate the optimal dose of daily oral E.halliii treatment with respect to safety, improvement in insulin sensitivity (clamp) and reduced liver fat content (NAFLD/NASH on liver MRI) in male subjects with metabolic syndrome.

Study objective

We hypothesize that daily oral administration of increasing dosages of Eubacterium hallii, an anaerobic intestinal bacterial strain, can exert beneficial effects on insulin sensitivity and liver fat.

Study design

0,1,2,4,5,6 weeks

Intervention

increasing daily dosages of eubacterium hallii (10e6, 10e8 and 10e10 cells/ml) for 4 weeks in male subjects with metabolic syndrome

Contacts

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Eligibility criteria

Inclusion criteria

-Caucasian obese subjects with metabolic syndrome (males, aged 21 to 69 years-old; body mass index (BMI) 25 to 43 kg/m2, fasting plasma glucose > 5.6 mmol/l, fasting triglycerides > 1.7 mmol/l, waist circumference > 102 cm)

- No concomitant medication

- Regular stool pattern

Exclusion criteria

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

- Cholecystectomy

- Use of medication including proton pump inhibitors

- 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 weightloss of >10% in the last months

- Overt untreated GI disease/abnormal bowelhabits;

- Levels of plasma aspartate aminotransferase (ASAT) and alanine aminotransferase (ALAT) are 2.5 times or more the upper limit of the normal range

- 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)

- Overt DM2

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2014
Enrollment:	27
Type:	Actual

Ethics review

Positive opinion

Date:	22-11-2014
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	NL4775
NTR-old	NTR4913
Other	: MEC 2014_215

Study results