Effect of Multiple healthy donor intestinal microbiota infusions on non Alcoholic Steatosis Hepatis (NASH) and vascular function; the MASH trial

No registrations found.

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

Summary

ID

NL-OMON20681

Source
NTR

Brief title
MASH trial

Health condition

NAFLD/NASH;

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The primary outcome parameter is reversal of steatosis hepatis without worsening of fibrosis,

as assessed by liver biopsy using the Brunt classicification between baseline and after 6 months

Secondary outcome

-changes in (small) intestinal microbiota and bacterial translocation after fecal transplantation

- changes in MRI based liver and vascular wall imaging after fecal transplantation

- changes in plasma (monocyte) and subcutaneous adipose tissue inflammatory markers after fecal transplantation

Study description

Background summary

with this study we would like to investigate whether (small) intestinal microbiota are causally involved in NASH and chronic low grade inflammation in obese humans via multiple fecal transplantations using either lean (preferably vegan/vegetarian) fecal donors (allogenic) or own (autologous) feces

Study objective

we would like to investigate whether multiple fecal transplantations using either allogenic (lean preferably vegetarian/vegan donor) or autologous (own) donors have a beneficial effect on non alcoholic steatohepatitis (NASH) using biopsy and MRI images and which intestinal microbiota are involved

Study design

liver/ fat biopsy and MRI imaging at 0 and 6 months

intestinal microbiota analyses and plasma inflammatory markers at baseline, 8,16 and 24 weeks

Intervention

multiple lean (preferably vegetarian/vegan) donor fecal transplantations

Contacts

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Eligibility criteria

Inclusion criteria

Patients: obese subjects (BMI > 25 kg/m2, male or postmenopausal female subjects aged 21-69 years old without concomitant medication) with biopsy-proven NASH

Donors:lean (BMI 20-25k/gm2) preferably vegan/vegetarian male / postmenopausal female subjects, Aged 21 to 69 years , no concomitant medication,

Exclusion criteria

Patients:

- history of cardiovascular disease, Cholecystectomy, heavy alcohol use or immunodeficiency;

- use of any medication including proton pump inhibitors (PPI) , oral anticoagulants and/or oral antibiotics in the past three months, plasma aspartate aminotransferase (ASAT and alanine aminotransferase (ALAT) are 2.5 times or more the upper limit of the normal range

- Other causes of liver diseases besides NAFLD/NASH (e.g. hemachromatosis, auto-immune hepatitis, hepatitis B or C, alcoholic steatohepatitis)

donors: use of medication ,fecal bacterial and viral pathogens including C.difficile,

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2014
Enrollment:	54
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-12-2013
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	NL4189
NTR-old	NTR4339
Other	: MEC 13/207
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A