The role of gut microbiota in CHOline and CARnitine metabolism on vascular inflammation in metabolic syndrome; the ChoCar-trial

No registrations found.

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

Summary

ID

NL-OMON24732

Source
Nationaal Trial Register

Brief title
ChoCar-trial

Health condition

subjects with metabolic syndrome; intestinal choline and carnitine metabolism; TMAO; vascular inflammation

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

changes in postprandial choline and carnitine metabolism (d6-labeled choline and d3-labeled carnitine) and fecal gutmicrobiota composition between baseline and 2 weeks after vegetarian/vegan microbial transplantation

Secondary outcome

changes in vascular/intestinal wall inflammation (PETCT) between baseline and 2 weeks after vegetarian/vegan microbial transplantation.

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

Study description

Background summary

in this trial we would like to investigate the causality of intestinal microbiota in carnitine/choline metabolism and TMAO levels in relation to PETCT based inflammation in male subjects with metabolic syndrome treated either with lean vegetarian/vegan donor (allogenic) or own feces (autologous)

Study objective

We would like to investigate whether intestinal choline and carnitine metabolism by microbiota is a transmissible trait using fecal transplantation from either allogenic (lean vegetarian/vegan) or autologous (own) donors on a) postprandial choline (oral d6-labeled choline) and carnitine (oral d3-labeled carnitine) metabolism, b) vascular inflammation (PETCT) and c) subcutaneous adipose tissue inflammation in male obese subjects with metabolic syndrome.

Study design

0 and 2 weeks

Intervention

lean vegetarian/vegan donor feces

Contacts

Public

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Eligibility criteria

Inclusion criteria

patients: treatment naive male obese patients with metabolic syndrome; 21 to 69 years-old; body mass index (BMI) 30 to 43 kg/m2

fecal donors: male healthy, lean, vegetarian/vegan (21 to 69 years old, BMI between 20 and 25 kg/m2, no medication use)

Exclusion criteria

patients: Supplement use (including vitamin/choline/carnitine supplements, energy drinks and carnitine-enriched soymilk) is not allowed. Other exclusion criteria are a medical history of a cardiovascular event (myocardial infarction/stroke), cholecystectomy, use of medication including antacids and oral antibiotics in the past three months and immunodeficiency.

donors: Presence of fecal bacterial pathogens and viruses; history of a cardiovascular event (myocardial infarction/stroke), cholecystectomy, use of medication including antacids and oral antibiotics in the past three months; Supplement use (including vitamin/choline/carnitine supplements, energy drinks and carnitine-enriched soymilk)

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:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	28-12-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39717
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4188
NTR-old	NTR4338
CCMO	NL41928.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39717

Study results

Summary results
N/A