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

Gepubliceerd: 28-12-2013 Laatst bijgewerkt: 15-05-2024

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...

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

Samenvatting

ID

NL-OMON24732

Bron
NTR

Verkorte titel
ChoCar-trial

Aandoening

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

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: CVON

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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)

Doel van het onderzoek

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.

Onderzoeksopzet

0 and 2 weeks

Onderzoeksproduct en/of interventie

lean vegetarian/vegan donor feces

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	50
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-12-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39717
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A