‘Effect of Faecal Transplantation on Satiety, Sarcopenia, Inflammation and Chemotherapy Toxicity in patients with Metastasized Oesophageal and Gastric Cancer’

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

Samenvatting

ID

NL-OMON27424

Bron
NTR

Verkorte titel
TRANSIT study

Aandoening

patients with metastasized or locally advanced oesophageal or gastric cancer receiving standard first-line palliative chemotherapy (capecitabine/oxaliplatin).
FMT
microbiota

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Effect of fecal transplantation (from healthy obese donors) on feceal microbiota composition in relation to satiety (questionnaires, biomarkers,) and metabolism (REE) in patients with metastasized or locally advanced oesophageal or gastric cancer receiving standard first-line palliative chemotherapy (capecitabine/oxaliplatin).

Toelichting onderzoek

Achtergrond van het onderzoek

Sarcopenia, the loss of skeletal muscle mass and strength, is associated with increased risk of chemotherapy toxicity and poor overall survival in patients with cancer due to poor nutritional status. Previous animal data suggest that faecal microbiota transplantation (FMT) from obese donors can drive weight gain. We will thus study in cancer patients whether obese FMT improves sarcopenia, satiety (appetite) and subsequent nutritional status.

Doel van het onderzoek

We postulate that faecal microbiota transplantation (FMT) from obese donors in patients with cancer can improve satiety (appetite) and subsequently nutritional status. Secondly, FMT might restore the gut barrier function and hence reduce systemic inflammatory tone.

Onderzoeksopzet

0,4, and 12 weeks

Onderzoeksproduct en/of interventie

FMT

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Male or female with metastasized or locally advanced oesophageal and/or gastric cancer receiving standard first-line palliative chemotherapy (capecitabine/oxaliplatin)

- Age between 30-70 years

- Meeting the criteria for sarcopenia, using computed tomography (CT)-scan: the L3 muscle area surfaces will be normalized for patient height to calculate the L3 muscle index and expressed in cm2/m2. The cutoff values used for sarcopenia are 52.4 cm2/m2 for men and 38.5 cm2/m2 for women, based on the method of Prado et al1

- Meeting the International Classification of Functioning, Disability and Health (ICF)28, WHO 1, 2 or 3.

- Stable medication use, all subjects use PPI.

- Subjects should be able and willing to give informed consent

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

- Smoking, XTC, amphetamine or cocaine abuse

- Alcohol abuse (>3/day)

- Cholecystectomy

- HIV infection with a CD4 count < 240

- Chronic nausea, altered taste sensation, swallowing difficulties or mechanical obstruction due to the malignancy.

- History of neurological disease or psychiatric disorder.

- Patients with diabetes mellitus (there are several studies indicating that a high level of NLR may reflect ongoing vascular inflammation and play an important role in the pathophysiology of DM and even prediabetes) 29.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2016
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-07-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5829
NTR-old	NTR5984
Ander register	: METC 2016_025

Resultaten