# ‘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**
Nationaal Trial Register

**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