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

No registrations found.

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

Summary

ID

NL-OMON27424

Source
Nationaal Trial Register

Brief title
TRANSIT study

Health condition

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

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Effect of fecal transplantation on:

1. Sarcopenia (measured by CT-scan).

2. Body composition (BIA)

3. Systemic inflammation and gut barrier function (CRP, plasma interleukins/LPS binding protein levels and fecal calprotectin) in relation to energy metabolism as measured by resting energy expenditure (REE).

4. Chemotherapy toxicity, graded with the Common Terminology Criteria for Adverse Events (CTCAE)11

5. Treatment response measured by CT-scan at baseline and after the first 3 cycles of chemotherapy (week 12).

6. Overall survival (defined as the number of days of survival after PA diagnosis).

Study description

Background summary

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.

Study objective

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.

Study design

0,4, and 12 weeks

Intervention

FMT

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-08-2016
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion Date:	21-07-2016
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	NL5829
NTR-old	NTR5984
Other	: METC 2016_025

Study results