Intestinal microbiota in colorectalcancer

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29314

Bron
Nationaal Trial Register

Verkorte titel
Microbiota in CRC

Aandoening

Intestinal microbiota, microbiome, Colorectal cancer treatment, chemotoxicity, respons
Intestinale microbiota, microbioom, colorectaal carcinoom behandeling, chemotoxiciteit, respons

Ondersteuning

Primaire sponsor: AZM
Overige ondersteuning: Stichting Jules Coenegracht Sr.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Microbiota composition before, during and after 3 cycles systemic treatment with capecitabine or TAS-102 related to respons & chemotoxicity

Toelichting onderzoek

Achtergrond van het onderzoek

Purpose

Investigate in patients with metastatic and/or irresectable colorectal cancer treated with systemic treatment with capecitabine or TAS-102 whether:

1.Intestinal microbiota composition can act as a predictor for response.

2.Intestinal microbiota composition changes during systemic treatment and its relation to chemotoxicity.

Background

Gut microbiota and host determinants evolve in symbiotic and dependent relationships resulting in a personal ecosystem. In vitro studies showed prolonged and increased response to 5-fluorouracil, a fluoropyrimidine, in the presence of a favorable microbiota composition. Capecitabine and TAS-102 are both fluoropyrimidines used for systemic treatment in colorectal cancer patients.

Methods

An explorative prospective multicenter cohort study in the Maastricht University Medical Centre+, Catharina Hospital and Zuyderland Medical Centre will be performed in 66 patients. Before, during, and after three cycles of systemic treatment with capecitabine or TAS-102, fecal samples and questionnaires (concerning compliance and chemotoxicity) will be collected. The response will be measured by CT/MRI using RECIST-criteria. Fecal microbiota composition will be analyzed with 16S rRNA next-generation sequencing. The absolute bacterial abundance will be assessed with quantitative polymerase chain reaction. Multivariate analysis will be used for statistical analysis.

Conclusions

We aim to detect a microbiota composition that predicts if patients with metastatic and/or irresectable colorectal cancer will respond to systemic treatment and/or experience zero to limited chemotoxicity. If we are able to identify a favorable microbiota composition, fecal microbiota transplantation might be the low-burden alternative to chemotherapy switch in the future.

Doel van het onderzoek

The microbiota composition can predict if patients with metastatic and/or irresectable CRC will respond to systemic treatment and/or experience zero to limited chemotoxicity. Secondly, we postulate that patients who retain the same favorable microbiota composition during systemic treatment will respond and/or experience zero to limited chemotoxicity.

Onderzoeksopzet

Before, during and after 3 cycles systemic treatment with capecitabine or TAS-102 fecal samples and questionnaires will be collected.

Onderzoeksproduct en/of interventie

An explorative prospective multicenter cohort study in the Maastricht University Medical Centre+, Catharina Hospital and Zuyderland Medical Centre will be performed in 66 patients. Before, during, and after three cycles of systemic treatment with capecitabine or TAS-102, fecal samples and questionnaires (concerning compliance and chemotoxicity) will be collected. The response will be measured by CT/MRI using RECIST-criteria. Fecal microbiota composition will be analyzed with 16S rRNA next-generation sequencing. The absolute bacterial abundance will be assessed with quantitative polymerase chain reaction. Multivariate analysis will be used for statistical analysis.

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients diagnosed with metastatic and/or irresectable CRC who will be treated with oral capecitabine (with or without intravenous bevacizumab) or oral trifluridine/tipiracil (TAS-102).

• Aged 18 years or older.

• Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Proven Microsatellite instability (MSI).

• Has not received any prior systemic therapy for the treatment of CRC during the previous 4 weeks prior to start of the current line of capecitabine or TAS-102.

• Patients treated with additional systemic treatments during planned treatment period.

• Radiotherapy within past 2 weeks prior to start.

• Therapeutic antibiotic use within past 3 months prior to start.

• Renal function: calculated creatinine clearance (Cockroft-Guilt) < 30 ml/min.

•Pregnant or nursing.

•Physically or mentally incapable or incompetent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2017
Aantal proefpersonen:	66
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2018
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	NL6571
NTR-old	NTR6957
Ander register	PMID: 28444508 : METC 16-4-234

Resultaten

Samenvatting resultaten

Aarnoutse, R., de Vos-Geelen, J. M. P. G. M., Penders, J., Boerma, E. G., Warmerdam, F. A. R. M., Goorts, B., Olde Damink, S. W. M., Soons, Z., Rensen, S. S. M., and Smidt, M. L. (2017) Study protocol on the role of intestinal microbiota in colorectal cancer treatment: a pathway to personalized medicine 2.0, International Journal of Colorectal Disease, 1-8.