Intestinal microbiota in colorectalcancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29314

Source
Nationaal Trial Register

Brief title
Microbiota in CRC

Health condition

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

Sponsors and support

Primary sponsor: AZM
Source(s) of monetary or material Support: Stichting Jules Coenegracht Sr.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2017
Enrollment:	66
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-01-2018
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	NL6571
NTR-old	NTR6957
Other	PMID: 28444508 : METC 16-4-234

Study results

Summary results

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.