Gut microbiome dynamics in metastasized or irresectable colorectal cancer: initiating a prospective multicenter cohort

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To analyze the gut microbiome in relation to response and toxicity in a prospective cohort of patients with newly diagnosed metastasized or irresectable colorectal carcinoma treated with standard systemic therapy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON52467

Source
ToetsingOnline

Brief title
GIMICC

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: grant UMCG Kanker Research Fonds

Intervention

Keyword: colorectal cancer, gut microbiome

Outcome measures

Primary outcome

To predict which patients will develop a partial or complete response to systemic treatment based on the characteristics of the gut microbiome.

Secondary outcome

- To determine which bacteria in the pre-treatment gut microbiome predict serious side effects of conventional systemic anti-tumor therapy for metastatic or irresectable colorectal cancer.

- To determine the relation between alterations of the gut microbiome and bacterial metabolites during systemic anti-tumor therapy and efficacy and toxicity of systemic anti-tumor therapy.

Study description

Background summary

A better understanding of the composition, function and dynamics of the gut microbiome before and during systemic anti-tumor therapy might help to identify factors that can be influenced during the treatment of patients with metastasized or irresectable colorectal carcinoma.

Study objective

To analyze the gut microbiome in relation to response and toxicity in a prospective cohort of patients with newly diagnosed metastasized or irresectable colorectal carcinoma treated with standard systemic therapy.

Study design

A prospective multicentre observational, investigator-sponsored study.

Study burden and risks

In short, patients will be informed about this study by their own oncologist. When informed consent is given, patients will collect fecal samples at home prior to treatment and at 3 months after start of treatment at the time of response evaluation using a standard stool-collection-kit. At the day of sampling, patients fill out a brief questionnaire about established factors that can change the microbiome such as concurrent use of antibiotics or proton pump inhibitors. Patients will send the fecal sample and questionnaire by mail to the UMCG. During the next visit at their local hospital, 4 tubes of blood are collected and sent to the UMCG for storage. The risk of fecal collection and blood draws is considered negligible. Radiological response evaluation takes place approximately 12 weeks after start of therapy using RECIST v1.1 as part of standard treatment. No extra hospital visits are required.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 years
- Patients with histologically confirmed CRC with an indication for neo-adjuvant or palliative systemic anti-tumor therapy (ANY combination of chemotherapy with/without anti-VEGF of anti-EGFR therapy, or immunotherapy)
- Measurable disease according to RECIST v1.1.
- Stored pathological specimens available
- Life expectancy >= 12 weeks
- Signed Informed Consent Form
- Ability to comply with protocol

Exclusion criteria

- Previous (neo)adjuvant chemotherapy < 6 months
- Previous radiotherapy on the small or large intestine < 1 month
- Previous surgery of the small or large intestine < 1 month
- Uncontrolled inflammatory bowel disease
- Participation in a study with a potential effect on the gut microbiome

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-09-2020
Enrollment:	300

Type:	Actual

Ethics review

Approved WMO Date:	07-11-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-03-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	08-06-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-09-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT03941080

Register
CCMO

ID
NL69836.042.19