Striving for earlier detection and optimization of treatment and prognosis for patients with early-onset colorectal cancer (EOCRC); BIO-EOCRC study

Published: 30-12-2024
Last updated: 18-01-2025

To develop a prediction model for EOCRC patients that estimates the risk of having low HRQoL one year after inclusion based on a comprehensive set of predictors including patient characteristics, disease and treatment factors, lifestyle variables...

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

Summary

ID

NL-OMON57209

Source
ToetsingOnline

Brief title
BIO-EOCRC

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
colorectal cancer, early-onset colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: MLDS

Intervention

Keyword: Early detection, Early-onset colorectal cancer, Pathogenesis

Outcome measures

Primary outcome

Low global QoL score measured by the EORTC-C30 questionnaire one-year after inclusion in early-onset colorectal cancer patients aged 18-49 years.

Secondary outcome

- Characteristics of the individual (sociodemographic characteristics (e.g. age, sex, work, household, BMI), disease characteristics (e.g. sidedness, tumor subsite (colon subsite or rectum), TNM stage, MSS/MSI, RAS/RAF mutational status, metastatic sites, CEA, LDH) and psychosocial characteristics).
- Characteristics of the environment (Treatment characteristics & Lifestyle outcomes).
- Medical history / conditions, survival outcomes (overall survival, progression free survival, disease free survival).
- Microbioma outcomes
- Blood and stool-based biomarkers.
- Tumor genetics, biology and carcinogenesis based on WGS and tissue biopsies of tumor and surrounding mucosa.

Study description

Background summary

The incidence of early-onset (<50 years) colorectal cancer (EOCRC) is rapidly increasing (average annual increase 2-4%). Importantly, EOCRC shows a distinct tumor biology with more often advanced stages at presentation and this results in worse survival. In addition, a cancer diagnosis and treatment(s) can lead to long-term morbidity and disrupt physical, cognitive, and psychosocial development, which can result in a reduced health-related quality of life (HRQOL) in this young population. This has led the US National Cancer Institute to rank this area of unmet need as research priority. Exposomes (including diet, lifestyle and microbiome) in combination with novel genetic variants have been suggested to play an etiological role in EOCRC carcinogenesis. However, data are scattered and based on retrospective studies, with contradicting results. Prospective multiomics studies are warranted for a better understanding of biology and pathogenesis and to enable analysis of diagnostic biomarkers to develop both preventive and early detection strategies.

Study objective

To develop a prediction model for EOCRC patients that estimates the risk of having low HRQoL one year after inclusion based on a comprehensive set of predictors including patient characteristics, disease and treatment factors, lifestyle variables and psychosocial factors.

Study design

Monocenter, prospective, observational cohort study.

Study burden and risks

On an individual level, patients who participate are asked to complete questionnaires at baseline and on an annual basis for at least 10 years concordant with the COMPRAYA (2.0) study. All sample collections (faeces, serum) will take place at three to five time points during standard follow up hospital visit: at baseline and during or after treatment at 3 months (only if patient receives systemic treatment), 6 months and 12 months and at disease recurrence after treatment with curative intent; tissue biopsies and blood sample for whole genome sequencing (WGS) will only take place at baseline. A tumor biopsy is optional in case of recurrent disease. The collection of blood and faeces is minimally invasive and the risks are negligible. Primary tumor and colon biopsies are performed during standard of care endoscopies and the general risks of colonoscopy and tissue biopsies apply. WGS will be performed on biopsy from the primary tumor or metastatic lesion and on blood sample and falls under the routine diagnostics for molecular analysis in metastatic colorectal cancer. All safety measures and procedures will be performed according to local guidelines. Patients will not experience direct benefit from participation in the BIO-EOCRC study. However, by participating, patients will contribute to a better insight in the biology and pathogenesis of early-onset

(<=50 years) colorectal cancer (EOCRC).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients with locoregional or metastatic colorectal cancer
- Histologically proven CRC
- Age 18 - 49 years at time of first CRC diagnosis
- Able to understand the informed consent form
- Provide written informed consent

Exclusion criteria

- Mentally incompetent patients based on the opinion of treating physician
- Inability to understand the Dutch language

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-01-2025
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	30-12-2024
Application type:	First submission
Review commission:	METC NedMec

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
CCMO	NL87254.041.24