Follow-up after surgery for colorectal cancer: the prospective, multicentre FUTURE-primary implementation study.

Published: 23-08-2021
Last updated: 30-01-2025

Primary Objective: The primary objective of this study is to implement a patient-led home-based follow-up approach in patients treated surgically for CRC. A successful implementation of the patient-led aspect is defined as 75% or less of optional...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON52113

Source
ToetsingOnline

Brief title
FUTURE-primary

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colon cancer, Colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Colorectal cancer, Follow-up, Homebased, Patient in the lead

Outcome measures

Primary outcome

The primary endpoint of this study is a successful implementation of patient-led home based follow-up in patients under surveillance for CRC. Patient-led follow-up will be considered successful if the used optional follow up rate is below 75%. The rationale being that if more than 75% of the optional follow up moments are used, the added value of providing patients with a say in the frequency of their postoperative surveillance is minimal, as most will opt for the maximum frequency anyway.

Secondary outcome

Secondary endpoints of the study will be:

* Successful implementation of home-based sampling by the patients themselves, defined as 25% or more of all scheduled or optional CEA assessments actually performed in blood collected by the patients themselves using the self-administered blood-sampling kit.

* Quality of life: measured by the QLQ-C30 43,44 (Appendix D)

* Health-related quality of life and the QLQ-CR29 45 (Appendix E)

* Momentary quality of life: measured by ecological momentary assessment using the Global health status of the EORTC QLQ-C30 (Appendix F)

* Anxiety: measured by The State-Trait Anxiety Inventory: Six-Item Short-form (STAI-6) 46,47 (Appendix G)

* Fear of cancer recurrence: measured by the Assessment of Survivor Concerns -

Cancer Worry subscale (ASC-CW) 48 (Appendix H)

* Cost-effectiveness: incremental costs and effectiveness will be determined:

• Utility measure: EQ-5D-5L questionnaire 49 (Appendix I)

• Intramural costs: assessed by review of patient records

• Extramural costs: assessed by a selection of relevant questions from the Medical Consumption Questionnaire (iMCQ) form the institute of Medical Technology Assessment.50 (Appendix J)

o Questions 14, 15 and 18 - 31 are omitted from the original questionnaire.

* Survival: both overall and cancer-specific, calculated from the date of surgical resection to the date of death or last follow-up.

* Relation between coping style and follow-up preferences: measured by the Threatening Medical Situations Inventory (TMSI) (Appendix K)

* Satisfaction of the patient-led home-based follow-up by a two-item questionnaire at the last follow-up (Appendix L)

Study description

Background summary

The available literature implies that intensive postoperative surveillance has no impact on (cancer-specific) survival outcomes in patients after curative intent surgery for CRC, critical appraisal of the current follow-up practice and guidelines is needed. Although patients in the referenced randomized controlled trials were included roughly 5 - 15 years ago, treatment for recurrent colorectal cancer has seen little to no change since then. Therefore, efforts to improve the current standard of follow-up in patients with CRC should focus on ameliorating quality of life and cost-effectiveness, rather than survival. It provides an opportunity to support patients emotionally, to evaluate treatment effects and complications, and to inform them on their individual prognosis. This is especially true considering the growing importance of value based healthcare and patient reported outcomes in medicine.

We therefore propose a patient-led home-based follow-up approach. This follow-up strategy primarily consists of CEA level monitoring at home, but additional counselling/diagnostic testing remains possible if desired by patients. In this way we hope to meet the individual needs of patients during follow-up and to improve quality of life outcomes, while achieving equal or greater societal cost-effectiveness.
The currently developed implementation study aims to evaluate if such a patient-led home-based follow-up approach is successful, improves quality of life, reduces anxiety and lessens fear of cancer recurrence during the years after surgical treatment of CRC.

Study objective

Primary Objective:
The primary objective of this study is to implement a patient-led home-based follow-up approach in patients treated surgically for CRC. A successful implementation of the patient-led aspect is defined as 75% or less of optional follow-up moments (i.e. CEA measurements) utilized.

Secondary Objective(s):
The secondary objectives of this study are:
• To measure successful implementation of out of hospital CEA measurement
A successful implementation of the home-based aspect is defined as 25% or more of all CEA measurements actually being performed at home by the patients themselves through use of a fingerprick lancet or TAP-II device.
• To compare the quality of life with an in-hospital standard of care related cohort
• To compare anxiety
• To compare the fear of cancer
• To compare overall and cancer-specific survival
• To determine and compare the cost-effectiveness of follow-up
• To predict follow-up preferences based on patients* coping style
• To measure patient satisfaction at the end of the follow-up period

Study design

The FUTURE-primary trial is a multicentre prospective regional implementation study of a patient-led home-based follow-up approach after curative treatment for CRC. Follow-up will be carried out for up to five years after surgery.

Follow-up will be performed in accordance with the current Dutch national guidelines. Blood sampling will in principle be performed at home, while the actual CEA measurements will be centralized and interpretation of the results will be done by the treating physician in the participating centre (the centre where the initial treatment was performed). Blood sampling is planned every six months during the first two years after inclusion and yearly thereafter. One

year after surgery medical imaging (according to local practices) and clinical evaluation will be scheduled. In hospital evaluation will only be performed in case of abnormal CEA values or if desired by the patient (in case of normal CEA levels). Subsequent use of medical imaging is used according to national guidelines and local practices. The frequency of patient-initiated CEA measurements and in-hospital evaluations cannot exceed the maximum amount of the current Dutch national guidelines unless clinically indicated (e.g. CEA increase or symptoms). The Dutch national guidelines advise CEA measurements every three months during the first two years and every six months thereafter. The desired frequency can be changed by the patient at any time.

Study burden and risks

We hypothesize that a patient-led home-based follow-up can be implemented successfully. In addition, we hypothesize that such an approach improves quality of life outcomes and reduces anxiety and fear of cancer recurrence when compared with the contemporary in-hospital approach. These hypotheses were substantiated by way of systematic patient-interviews. We also expect the home based approach to achieve an equal or greater cost-effectiveness.
This study will provide valuable insights in the questions surrounding follow-up, mainly whether current follow-up practices based on frequent hospital visitations can be replaced by a more modern, home based follow-up with an emphasis on shared-decision making. Therefore, our aim is to identify an optimal, patient-tailored way of monitoring patients after surgical treatment of CRC. An individualized home based surveillance approach fits well in the current era of value based healthcare and patient reported outcomes. The results of this study will be used to create evidence based guidelines for long-term surveillance of these patients and could potentially lead to similar studies and approaches in other suitable patient populations.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age >= 18 years
• Histologically confirmed colorectal adenocarcinoma without distant metastasis and treated with curative intent surgical resection less than 6 months ago
• Scheduled or currently undergoing postoperative surveillance according to national guidelines

Exclusion criteria

• Patients with a severely complicated postoperative course, needing in hospital follow-up longer than 6 months postoperatively
• Patients enrolled in other studies that require strict adherence to any specific follow-up practice with regular imaging - yearly or more frequent - of the abdomen and/or thorax
• Patients with comorbidity or other malignancy that requires imaging of the abdomen and/or thorax every year or more frequent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-09-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-01-2025
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCTnummervolgt
CCMO	NL77810.078.21