Follow-up after surgery for colorectal cancer: the FUTURE-primary implementation study

No registrations found.

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

Summary

ID

NL-OMON27170

Source
Nationaal Trial Register

Brief title
FUTURE-primary

Health condition

Colorectal cancer
Quality of life
Shared decision making
Follow-up
Cost-effectiveness

Sponsors and support

Primary sponsor: Dr. D.J. Grünhagen, Erasmus MC Cancer Institute
Source(s) of monetary or material Support: Funding for the study has been provided by the Dutch Cancer Society (KWF)

Intervention

Outcome measures

Primary outcome

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 outcome

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.
• 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 description

Background summary

The FUTURE-primary study is a multicentre prospective regional implementation study of a patient-led home-based follow-up
approach after curative treatment for colorectal cancer treatment. 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 objective

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.

Study design

All of the retrospective questionnaires, with the exception of the ASC-CW, will be completed at baseline and every 6 months thereafter in the first three years, in the last 2 years the questionnaires will be completed annually or when patients leave the study due to disease recurrence. The ASC-CW scale will be completed once at 12 months following inclusion and in case of no disease recurrence. The ecological momentary assessment of momentary quality of life will be performed for the entire duration of the study, regardless of disease recurrence.

Contacts

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Eligibility criteria

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
• Written informed consent by the patient

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
• Inability to complete the questionnaires due to illiteracy and/or insufficient proficiency of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-08-2021
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-10-2021
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	NL9836
Other	METC Erasmus MC : MEC20210499

Study results