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

Gepubliceerd: 28-10-2021 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27170

Bron
NTR

Verkorte titel
FUTURE-primary

Aandoening

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

Ondersteuning

Primaire sponsor: Dr. D.J. Grünhagen, Erasmus MC Cancer Institute
Overige ondersteuning: Funding for the study has been provided by the Dutch Cancer Society (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Contactpersonen

Publiek

Erasmus MC
Kelly Voigt

0107042125

Wetenschappelijk

Erasmus MC
Kelly Voigt

0107042125

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-08-2021
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-10-2021

Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9836
Ander register	METC Erasmus MC : MEC20210499

Resultaten