Towards patient-led follow-up after curative treatment of stage II and III colorectal cancer

Published: 11-01-2021
Last updated: 13-12-2022

We hypothesize more than 90% of the participants in the in-hospital, standard-of-care follow-up will contact the hospital during the study period and 40-50% of the patients in the patient-led, home-based follow-up will contact the hospital between...

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20781

Source
Nationaal Trial Register

Brief title
DISTANCE-trial

Health condition

Colorectal cancer

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: ZE&GG, ZonMw

Intervention

Outcome measures

Primary outcome

Primary endpoint is the proportion of participant who have contacted the hospital between 12 and 24 months after curative surgery.

Secondary outcome

Secondary endpoints are quality of life, fear of cancer recurrence, patient satisfaction, cost-effectiveness and survival.

Study description

Background summary

Rationale: Colorectal cancer (CRC) is a common cancer in The Netherlands. After curative surgical resection, approximately 30% of stage I-III CRC patients develop a recurrent tumour or metastases. Patients are currently followed for five years after curative surgical resection. However, intensified follow-up after curative surgical resection has shown no effect on survival. Therefore, patient organisations and policy makers call for a more patient-centred, tailored follow-up. Objective: To successfully implement patient-led, home-based follow-up in six hospitals in the Netherlands. Study design: Stepped-wedge clustered randomised trial (SW-CRT) conducted in six centres. During the trial, three centres will implement patient-led, home-based follow-up after six months, the other three centres will implement patient-led, home-based follow-up after 12 months of participation. After the study, all centres will likely continue their patient-led, home15 based follow-up programs. Study population: Patients with stage pT2-4N0M0 or pT1-4N1-2M0 CRC, who are 18 years or older and have been free of disease for 12 months after curative surgical resection. Intervention: A patient-led home-based follow-up plan for stage pT2-4N0M0 or pT1-4N1-2M0 CRC patients, treated by curative surgical resection, starting 12 months after resection. Comparison: The regular, in-hospital follow-up care following guidelines of the participating centre. Main study parameters/endpoints: Primary endpoint is the proportion of patients who had contact with the hospital regarding CRC follow-up care between 12 and 24 months after curative surgical resection. Secondary endpoints are quality of life, fear of cancer recurrence, patient satisfaction, cost-effectiveness and survival. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Compared to the usual care, patient burden will likely decrease, as patients will not have to visit the hospital as frequently as they are used to do. This will also benefit patients financially, as their travel expenses to the hospital will be omitted. Participating patients are already participating in the Prospective Dutch CRC cohort (PLCRC); they therefore already receive surveys on QoL, fear of cancer recurrence and patient satisfaction periodically. Thus, this study will not add to patient’s burden of reporting surveys. Also, there is no proven benefit of intensive follow-up for CRC. A previously conducted single-centre study has already showed promising results for a remote follow-up plan.

Study objective

We hypothesize more than 90% of the participants in the in-hospital, standard-of-care follow-up will contact the hospital during the study period and 40-50% of the patients in the patient-led, home-based follow-up will contact the hospital between 12 and 24 months after curative resection.

Study design

Questionnaires will be send at 12, 18 and 24 months after curative resection.

Intervention

A patient-led home-based follow-up plan for curatively treated stage II/III CRC patients, starting 12 months after surgery.

Contacts

Public
Radboud University Medical Center
H. Swartjes

-
Scientific
Radboud University Medical Center
H. Swartjes

-

Eligibility criteria

Inclusion criteria

- Patient has pT2-4N0M0 or pT1-4N1-2M0 primary colorectal carcinoma treated with surgical resection with curative intent; - Patient is aged ≥ 18 years; - Patient is willing to participate in the Prospective Dutch CRC cohort (PLCRC); - Patient is disease-free at 12 months after resection (assessed by CT thorax19 abdomen, CEA and colonoscopy).

Exclusion criteria

- Patient has macroscopically (R2) incomplete resections; - Patient needs in-hospital follow-up longer than 12 months postoperatively (e.g. patients with a severely complicated

postoperative course, or patients enrolled in other studies that require in-hospital follow-up consultations); - Patient has confirmed hereditary CRC

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2022
Enrollment:	360
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
N/A

Ethics review

Positive opinion

Date:	11-01-2021
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	NL9266
Other	METC Arnhem-Nijmegen : 2020-7105

Study results

Summary results
N/A