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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20781

Bron
Nationaal Trial Register

Verkorte titel
DISTANCE-trial

Aandoening

Colorectal cancer

Ondersteuning

Primaire sponsor: N/A
Overige ondersteuning: ZE&GG, ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Radboud University Medical Center
H. Swartjes

-

Wetenschappelijk

Radboud University Medical Center
H. Swartjes

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2022
Aantal proefpersonen:	360
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	11-01-2021
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	NL9266
Ander register	METC Arnhem-Nijmegen : 2020-7105

Resultaten

Samenvatting resultaten
N/A