Improving Care After colon canceR treatment in the Netherlands - Personalised care to Enhance quality of life -

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON20048

Source
Nationaal Trial Register

Brief title
ICARE

Health condition

Colon cancer

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Amsterdam
Source(s) of monetary or material Support: KWF / Stichting Alpe DuZes

Intervention

Outcome measures

Primary outcome

Quality of life (generic and disease specific)

Secondary outcome

1) Physical outcomes: Recurrence rate and mortality, presence and duration of cancer related physical problems (pain, bowel function, fatigue, sexual problems, adverse side-effects of chemotherapy, et cetera), number, sort and treatment of intercurrent signs and symptoms.

2) Psychosocial outcomes: Labour force participation, participation and experienced autonomy, emotional support, anxiety, depression and self-efficacy.

3) Number of diagnostic tests, referrals and related communication between secondary and primary care

4) Recurrence detection and protocol adherence

5) Attention to preventive care (change in smoking habits, physical activity, mean systolic blood pressure, and cholesterol levels)

6) Cost effectiveness

7) Patient satisfaction and preference of care at the end of the trial

Study description

Background summary

Rationale

It is expected that in 2020 more than 17.000 patients with colorectal cancer will be diagnosed in the Netherlands. To date, after initial treatment patients are included in a surgeon-led programme with the main focus on recurrence detection. However, patients often experience multiple physical and psychosocial problems in this phase. Currently, in secondary care these problems are not always encountered and only a small number of

distressed patients are identified and supported. Both the Dutch Health Council as the Dutch Cancer Foundation suggested more generalist care as a solution. Furthermore, for patients it would be preferable to be able to undergo rehabilitation as much as possible in their own environment. Evidence shows that web-based interventions for patient empowerment can improve care. An important development of these e-health facilities is the OncoKompas which is an e-health application which facilitates direct-to-user delivery of individualised healthcare.

Objective and hypothesis

The above mentioned developments are subject to the I CARE study. We hypothesize that general practitioner (GP) involvement improves both aftercare and preventive care resulting in improved quality of life and patients' satisfaction. Furthermore, a GP-led recurrence detection programme leads to at least equal detection of recurrences. Also we hypothesize that the implementation of an e-health application (OncoKompas) to support patients in managing their own revalidation and aftercare and adapting to a healthier life leads to more attention for multi-morbidity, preventive care resulting in an improved quality of life and patients' satisfaction. Finally, we hypothesize that GPs responsible for the recurrence detection programme will feel more responsible for aftercare which will enhance revalidation and quality of life.

Study design

The present study proposal consists of a multi-centre 2x2 factorial randomised controlled trial with a calculated total sample size of 300 patients, based on the EORTC QLQ-C30. Patients will be randomised in four groups; 1. usual follow-up visits and aftercare provided in secondary care (surgeon-led), 2. usual follow-up visits and aftercare provided in secondary care with additional use of the e-health application OncoKompas, 3. follow-up and aftercare in primary care (GP-led), and 4. follow-up and aftercare in primary care with additional use of the e-health application OncoKompas.

Study population

Patients with stage I, II, and III carcinoma located in the colon and rectosigmoid are eligible. Patients with temporary stoma and who receive adjuvant chemotherapy are also eligible.

Main study parameters/endpoints

Primary outcomes include quality of life and patient satisfaction. Secondary outcomes include physical outcomes, psychosocial outcomes, number of investigations, referrals and related communication between secondary and primary care, (time of) recurrence detection and protocol adherence, attention to preventive care, cost effectiveness, and preference of care at the end of the trial.

Study objective

We hypothesize that general practitioner (GP) involvement improves both aftercare and preventive care resulting in improved quality of life and patients' satisfaction. Furthermore, a GP-led recurrence detection programme leads to at least equal detection of recurrences. Also we hypothesize that the implementation of an e-health application (OncoKompas) to support patients in managing their own revalidation and aftercare and adapting to a healthier life leads to more attention for multi-morbidity, preventive care resulting in an improved quality of life and patients' satisfaction. Finally, we hypothesize that GPs responsible for the recurrence detection programme will feel more responsible for aftercare which will enhance revalidation and quality of life.

Study design

3, 6, 12, 24, 36, 48, and 60 months

Intervention

Aftercare after treatment of colon cancer in secondary care (usual care) or primary care.

Use of an interactive website (OncoKompas 2.) in half of patients

Contacts

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Eligibility criteria

Inclusion criteria

• Carcinoma located in the colon and rectosigmoid defined as a tumour located 15 cm above the anal verge by coloscopy or above the sacral promontory as seen preoperatively

• Stage 1, 2 and 3 carcinoma

• Surgical treatment with curative intent

• Qualified for routine follow-up attendance by surgeon according to the national guideline.

• Patients with temporary stoma and who received adjuvant chemotherapy are also eligible.

Exclusion criteria

• Stage IV colorectal tumours

• Hereditary colorectal cancer

• Colorectal cancer in patients with inflammatory bowel disease

• Rectal cancer

• (Sub)total colectomy or proctocolectomy

• History of second primary cancer (except basal cell carcinoma of the skin) within the last 15 years

• Participation in other (clinical) research, which will affect the outcome measurements of this trial

• Permanent open wounds after surgery or other conditions where specialised care is needed

• Any other condition that warrants increased intensity of surveillance with respect to colon cancer follow-up

• Not able to speak Dutch or English

Study design

Design

Intervention model:	Factorial
Allocation:	Randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-10-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53014
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5347
NTR-old	NTR5580
CCMO	NL51026.018.14
OMON	NL-OMON53014

Study results

Summary results

Trials. 2015 Jun 26;16:284. doi: 10.1186/s13063-015-0798-7.
Improving care after colon cancer treatment in The Netherlands, personalised care to enhance quality of life (I CARE study): study protocol for a randomised controlled trial.
Duineveld LA1, Wieldraaijer T2, van Asselt KM3, Nugteren IC4, Donkervoort SC5, van de Ven AW6, Smits AB7, van Geloven AA8, Bemelman WA9, Beverdam FH10, van Tets WF11, Govaert MJ12, Bosmans JE13, Verdonck-de Leeuw IM14, van Uden-Kraan CF15, van Weert HC16, Wind J17