Frequent CEA measurements in follow-up of colorectal carcinoma.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19879

Source
NTR

Health condition

follow-up
colorectal cancer
Carcinoembryonic Antigen

Sponsors and support

Primary sponsor: Univeristy Medical Center Groningen
Source(s) of monetary or material Support: ZonMW doelmatigheid

Intervention

Outcome measures

Primary outcome

The percentage of curatively treatable recurrent or metachronous metastatic disease in the intervention group in comparison with the control group.

Secondary outcome

1. Disease free survival, recurrent-free survival, overall survival;

2. Quality of Life in patients undergoing more intensified follow-up schemes;

3. Costs and effectiveness of introducing a software tool to support the frequent CEA measrurements.

Study description

Background summary

In this prospective randomized trial, a new follow-up protocol for patients curatively treated for colorectal cancer (CRC) is introduced. A national guideline for follow-up after CRC already exists, but adherence to this guideline is variable.

In the study, 10 Dutch hospitals will participate. Randomization is on hospital level, which practically means that a hospital is performing follow-up in the way it's used to, and after randomization, all patients in that hospital will participate in the new schedule, resulting in the fact that the last-randomized hospital will produce a large dohort of control group and a small cohort of intervention group patients.

In the intervention group, CEA will be measured more frequently and further imaging will be performed in case of rise in CEA. Of course regular imaging using CT scan and colonoscopy will be performed as well.

In monitoring this follow-up, a software tool called CEA-watch is used, which attends the surgeon when a patient has an increased CEA value and can easily produce letters and emails for informing patients.

Aim of this study is to find metastatic disease earlier than in regular follow-up, thereby increasing the chance to curatively treat these metastases.

Study objective

The percentage of curatively treatable metastatic disease after surgery for primary colorectal cancer can be increased by means of optimizing follow-up of colorectal carcinoma. Intensifying the follow-up by increasing frequency of CEA measurements, and performing CT scans if CEA rises, will reach the increase of this percentage. Curable treatment of metastatic disease is known to be associated with longer survival.

Study design

1. 1-10-2010: Start interventions schedule in firstly randomized participating hospitals;

2. 1-10-2011: Start intervention schedule in last randomized participating hospitals;

3. 1-7-2012: Stop intervention.

Intervention

After randomization at hospital level, all patients in that hospital will participate in the new follow-up scheme. This consists of increasing of the frequency of CEA measurement, and of performing an additinal CT scan if CEA values has risen significantly.

All patients in the intervention group will be imported in a software program, which exactly follows all CEA values and gives information on rise in CEA. Thereby the program is able to inform the patients of their CEA values quickly. Using this software has shown to reduce the incidence of hospital visits for patients.

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Eligibility criteria

Inclusion criteria

1. Patients with stage II- III –IV colorectal carcinoma after curative resection (R0 resection) from 1-1-2007;

2. All new patients with II-III-IV colorectal carcinoma eligible for curative resection;

3. Patients currently in follow-up, operated within 2 years after start study;

4. All patients need to be above 18 and capable of understanding the Dutch language.

Exclusion criteria

1. Patients with other malignancies except basocellular carcinoma of the skin;

2. Patients not medically fit for metastasectomy;

3. Patients with diagnosed syn- or metachronous incurable metastases at time of start study;

4. No written informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	1800
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2065
NTR-old	NTR2182
Other	ZonMW : 171002209
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A