Computer supported follow-up after curative treatment of colorectal cancer based on CEA

Published: 31-05-2010
Last updated: 02-05-2024

To increase the amount of curatively treatable metastasis and recurrences of CRCandmaking an evidence-based guideline for the use of CEA in the follow-up of CRC

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON34900

Source
ToetsingOnline

Brief title
Intensive CEA measurements in follow-up of colorectal carcinoma

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
cancer of the colon and rectum, colorectal malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW doelmatigheid subsidie

Intervention

Keyword: CEA, colorectal carcinoma, follow-up

Outcome measures

Primary outcome

The percentage of curatively treatable recurrences and/or metastases in the

intensive follow-up arm has to be > 15% higher than the percentage in the

control group

Secondary outcome

Survival, disease-free and recurrence free survival per follow-up arm

Study description

Background summary

CEA is a serum tumormarker used in follow-up for colorectal cancer in early diagnosis of recurrent disease or metachronous metastatic disease. If metastases or recurrences are diagnosed early, the percentage of curative treatment increases and with curative treatment, the overall survival of these patients increases.
The national guideline for determining and interpreting of CEA is not uniform and adherence of surgeons is low. There is need to optimize the follow-up of CRC with CEA as a cheap, available and sensitive marker.

Study objective

To increase the amount of curatively treatable metastasis and recurrences of CRC

and

making an evidence-based guideline for the use of CEA in the follow-up of CRC

Study design

Patients operated for CRC will be in follow-up after resection. To these patients, an intensive follow-up with the frequent determination of CEA is offered.

Approximately 10 hospitals join this study. The moment on which a hospital will be participating is randomized. So, there is regular follow-up until randomization and after this every patient will be offered the intensive follow-up protocol.

Study burden and risks

In the intensive follow-up schema, patients have to undergo vena punctions more often (every 8 weeks instead of every 12 weeks). Only the minimal risk associated with vena punctions is added.
However, patients will have policlinic controls less often.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

TxNxMo colorectal carcinoma, histologically confirmed
operation date 01-01-2007 or later
>18 years

Exclusion criteria

fit for metastectomy
dementia

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO

Date:	31-05-2010
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	24-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL31410.042.10