Optimization of serum CEA measurement for detection of resectable metastasis after curative treatment of colorectal carcinoma.
A prospective multicentre phase II study

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To evaluate the effectiveness of optimization of CEA measurements after curative resection of stage II, III and IV colorectal carcinoma. The short-term effectiveness will be quantified in percentage of patients that are eligible for curative...

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON30817

Source
ToetsingOnline

Brief title
CEA in follow-up for colorectal carcinoma

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
bowelcancer, intestinal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Ministerie van OC&W,Industrie,Sanofi-aventis

Intervention

Keyword: carcinoembryonic antigen, colorectal neoplasms, follow-up, oncology

Outcome measures

Primary outcome

Percentage of patients eligible for curative resection of liver- or lung

metastasis

Secondary outcome

Calculation of the optimal threshold values and measurement frequency of CEA

The correlation between CEA and helical CT abdomen/thorax: specifically whether

the metastasis can be localised when CEA values suggest metastastatic disease.

Evaluation of the logistic feasibility of the proposed follow-up scheme

Study description

Background summary

The primary goal of follow-up after curative treatment of cancer is to detect curable local recurrence or distant metastasis. In colorectal carcinoma potentially curable recurrent disease includes liver- and lung metastasis and sometimes local recurrence. Serum CEA as a tumour marker is an effective and cost-efficient method for early detection of recurrent disease and is the core in current follow-up guidelines. Up to now however, follow-up has not been very effective for prolonging survival.
A previous study has been undertaken to investigate why CEA, despite its

theoretical capacities, has failed to prolong survival in clinical practice.
Various reasons why CEA was not effective to increase survival could be determined; Method related reasons are the measurement frequency, threshold interpretation and anticipation on expected time of recurrent disease. Clinical reasons have been the ineffective utilization of the achieved lead time, mainly because suspected recurrent disease could not be localized, the delay in treatment and the limited treatment options, all in comparison to the present situation. Logistic reasons have been the limited adherence to follow-up guidelines by doctors and patients, including failure to testing due to false assumptions about CEA. General conclusion is that with relatively simple adaptations the effectiveness of CEA on early detection of recurrent disease might be increased significantly.

Study objective

To evaluate the effectiveness of optimization of CEA measurements after curative resection of stage II, III and IV colorectal carcinoma. The short-term effectiveness will be quantified in percentage of patients that are eligible for curative metastasectomy of liver- and lung metastasis.

Study design

Multicentre prospective fase II study

Intervention

Monthly measurement CEA from blood sample in the 2 years after curative resection.
Instead of CEA measurement every 3 months as advised in the current guidelines.

Study burden and risks

- Haematoma from vena puncture
- Anxiety caused by frequent vena punctures

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients with stage II-III-IV colorectal carcinoma that had curative treatment and are medically fit for metastasectomy. Patients should be above 18 and not mentally incapacitated

Exclusion criteria

Patients not medically fit for metastasectomy
Patients with diagnosed syn- or metachronous incurable metastasis at time of inclusion
No written informed consent

Study design

Design

Study phase:	2
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	180
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL15366.042.07