Development and Evaluation of a CEA Algorithm.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27002

Source
Nationaal Trial Register

Brief title
DECA study

Health condition

Maligne colorectal tumor.

Sponsors and support

Primary sponsor: None.
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The aim of the study is to create a serum CEA-measurement based algorithm of CEA rising. If the algorithm proves higher sensitivity of detecting recurrence, and therefore higher curable treatment, it can result in an application which helps professionals in health care, mainly general practitioners, with decision making. One should think of decisions like closer monitoring of CEA measurements, additional imaging based on serum CEA measurements

("CEA-triggered imaging") or referring to a specialist

Secondary outcome

When there is an algorithm created, the second aim is to compare CEA algorithm triggered imaging of ultrasonography of the liver with the regular follow up and the detection of recurrence. Also comparing the cost efficacy of it.

Study description

Background summary

Patients with colorectal cancer who underwent a curative resection are offered a follow up program of five years in the Netherlands to detect early recurrence. The follow up program consists of laboratory measurements, imaging and physical examination.
The serum Carcino-Embryogenic antigen (CEA) is known for detection of recurrence in colorectal cancer. Follow up schedules with CEA measurement have better survival compared without CEA measurements and is also cheap.
The Dutch national guideline 'colorectal carcinoma 2014' advises routine CEA measurements every three to six months in the first three years after resection and once annually in the following two years. If metastatic disease is detected and curative treatment was possible, the 5-year follow-up starts from that moment once again as mentioned above.
Furthermore, the guideline advises ultrasonography of the liver every six months for the first two years and once annually in the last three years after resection. An alternative for ultrasonography is abdominal computed tomography (CT) to detect recurrence, e.g. for patients with obesities because abdominal CT is known to have higher sensitivity compared to ultrasonography. For distant metastasis one might consider pulmonary imaging in patients with rectum cancer.
However, the sensitivity and specificity for detection of recurrence with CEA is not high, and there's no consensus of an absolute value of CEA measurement for triggered imaging.
In current literature and the guideline, it is not specified which percentage of raise in CEA should be a trigger to perform additional imaging. The lower limit of an acceptable raise in CEA, in combination with physical examination, is unknown. The study of Verberne et a showed that an intensified protocol with CEA and assessment on CEA rise increases the curable recurrence rate, rather than the standard protocol with absolute values. The FACS study uses an absolute CEA cutt-off point of 7 µg/l compared to baseline instead of slope analyses. It showed better specificity but at the cost of sensitivity.

Study objective

The pattern of repeated CEA-measures is linear linked to the recurrence of colorectal cancer.

Study design

Preoperative CEA measurement till the last follow up CEA measurement.

Intervention

None.

Contacts

Public
Zuyderland Medical Centre
Laura Koolen

+31613536836
Scientific
Zuyderland Medical Centre
Laura Koolen

+31613536836

Eligibility criteria

Inclusion criteria

Patients older than eighteen years of age after resection of colorectal maligne tumor with at least one serum CEA measurement in follow up.

Exclusion criteria

None, only if data showed no evidence of cancer.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	3000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-07-2019
Application type:	First submission

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	NL7882
Other	Zuyderland Medical Centre Heerlen : METCZ20180119

Study results