Development and Evaluation of a CEA Algorithm.

Gepubliceerd: 21-07-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27002

Bron
Nationaal Trial Register

Verkorte titel
DECA study

Aandoening

Maligne colorectal tumor.

Ondersteuning

Primaire sponsor: None.
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Preoperative CEA measurement till the last follow up CEA measurement.

Onderzoeksproduct en/of interventie

None.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None, only if data showed no evidence of cancer.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	3000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7882
Ander register	Zuyderland Medical Centre Heerlen : METCZ20180119

Resultaten