Frequent CEA measurements in follow-up of colorectal carcinoma.

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19879

Bron
NTR

Aandoening

follow-up
colorectal cancer
Carcinoembryonic Antigen

Ondersteuning

Primaire sponsor: Univeristy Medical Center Groningen
Overige ondersteuning: ZonMW doelmatigheid

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2010
Aantal proefpersonen:	1800
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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

Resultaten

Samenvatting resultaten
N/A