Prognostic Factors for treatment and follow-up of patients after colorectal surgery

Published: 25-09-2006
Last updated: 20-05-2024

the investigation and evaluation of certain serummarkers for inflammation and tumoractivity during the followup of colorectal neoplasms, and the applicability of these markers during the followup of these patients or the evaluation of the effect of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31685

Source
ToetsingOnline

Brief title
prognostic factors colorectal surgery

Condition

- Other condition
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer, gut cancer

Health condition

chemo- en radiotherapeutische voorbehandelingseffecten op maagdarm neoplasmata

Research involving

Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colorectal, factors, follow-up, prognostic

Outcome measures

Primary outcome

Parameters which will be evaluated are the following:

- CRP (C-Reactive Protein)

- Leucocytes

- CEA (Carcino Embrionic Antigen)

- flowcytometric measurement of CEA in activated macrophages

- flowcytometric measurement of M30 in activated macrophages

- flowcytometric measurement of Cytokeratine 18 in activated macrophages

- tumor regression by chemoradiation-therapy

Secondary outcome

not available

Study description

Background summary

Patients who recently underwent colorectal surgery for colorectal neoplasms will be followed during 6-9 months to evaluate recurrence. Recurrence of colorectal carcinoma occurs frequently, especially in the first one and a half years. It is quite hard to predict a recurrence. The carcino embrionic antigen(CEA) is a marker that is currently used to predict a recurrence. beside the CEA-measurement, a CT-scan is performed once a year. Sadly enough this method does not predict all recurrences. reasons why are, intervals that are too long between blood-sampling, errors in the samples, and the compliance of the patients.
If CEA is increased a CT-scan is made and with a proof of recurrence, the patient will be treated. CEA is also increasing on several other occasions and in those occasions a CT-scan is performed which were not neccesary. CEA is not thrustworthy as a parameter and can also be increased in other circumstances in the human body. To investigate if other parameters can be able to indicate a recurrence, a couple of thouroughly selected parameters will be investigated together with the CEA in the serum of these patients. Also new diagnostic methods in patients suffering from colorectal carcinoma will be investigated, for example flowcytometrical analysis.
patients suffering from rectal carcinoma who will be pre-treated with chemoradiaton therapy will be checked for tumor downsizing and lymphnode pathology pre en post chemoradiation therapy

Study objective

the investigation and evaluation of certain serummarkers for inflammation and tumoractivity during the followup of colorectal neoplasms, and the applicability of these markers during the followup of these patients or the evaluation of the effect of pretreatment in patients suffering from rectal carcinoma by chemoradiation therapy.

Study design

propective diagnostic research

Study burden and risks

except for the standard-procedure:

- blood-sampling every 1 to 2 months 8 tubes a 3 ml (18 ml) for 2 years

risc's:

- bleeding from the site of blood-sampling.
- infection of the site of blood-sampling

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

patient before pre-treatment of or who recently underwent (pre-treatment for) colorectal surgery for colorectal neoplasmata

Exclusion criteria

no exclusion criteria

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-11-2006
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	25-09-2006
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL14215.096.06