The predictive value of cytokines on response to preoperative chemoradiotherapy in patients with rectal cancer.

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Predictive factors are needed to discriminate chemoradiotherapy responders from non-responders and to individualize the treatment regime. Various cytokines play a role in processes affecting tumour growth and metastasis. Furthermore, cytokines might...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON37973

Source
ToetsingOnline

Brief title
CYTORECT

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectal cancer / rectum carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Oncologiecentrum Midden Nederland

Intervention

Keyword: cytokines, predictive value, preoperative chemoradiotherapy, rectal cancer

Outcome measures

Primary outcome

Identifying cytokines which can predict response to preoperative

chemoradiotherapy in patients with locally advanced rectal cancer.

Secondary outcome

not applicable

Study description

Background summary

Preoperative chemotherapy and radiotherapy are essential parts of rectal cancer treatment. The selection of patients eligible for preoperative chemoradiotherapy is currently based on pathological parameters and MRI-scan findings. However, some of these patients show a good or complete response to chemoradiation whereas others do not respond at all. Surgery is performed independent of the response to the therapy and is attended with substantial morbidity. If complete or good responders to preoperative chemoradiotherapy can be identified surgery could be omitted or postponed. In contrast, if non-responders to preoperative chemoradiotherapy can be identified beforehand or in an early stage, chemoradiotherapy can be omitted or stopped and surgery can be brought forward.

Cancer and cancer treatment result in an inflammatory response thereby cytokines are produced. Cytokines may also themselves influence therapy response. Various cytokines are abnormal expressed in colorectal cancer patients, are associated with colorectal cancer or determine response to chemoradiotherapy. Our hypothesis is that the varying levels of these circulating cytokines in the blood of rectal cancer patients may predict the response to preoperative chemoradiotherapy. Because of the explorative pilot

study design this is not a hypothesis based study.

Study objective

Predictive factors are needed to discriminate chemoradiotherapy responders from non-responders and to individualize the treatment regime. Various cytokines play a role in processes affecting tumour growth and metastasis. Furthermore, cytokines might influence treatment response. Therefore we want to investigate whether levels of circulating cytokines could predict response to preoperative chemoradiotherapy in patients with rectal cancer.

The main objectives of the study are:
- To identify which cytokines and corresponding levels can predict response to preoperative chemoradiotherapy in patients with locally advanced rectal cancer
- To determine the influence of surgery on the immune response, which can be measured by comparing blood plasma cytokine levels before and after tumour resection
- To determine whether blood plasma cytokine levels reflect tissue cytokine levels

Study design

This study is an explorative clinical pilot study with a duration of 1 year in which we will collect 5 ml of blood from a selection of rectal cancer patients during a regular puncture before, during and after preoperative chemoradiotherapy and before and after surgery. At these time points regular blood samples are taken thus no extra puncture will be performed. Standard procedure MRI-scans will be made before and after chemoradiotherapy. Cytokines will be measured in blood plasma and in tumour and healthy tissue from the resection specimen using multiplex immunoassays. Plasma cytokine measurements will be linked to pathological (tissue samples) and clinical response (MRI-scans) to identify which cytokines and corresponding levels can predict response to preoperative chemoradiotherapy in patients with locally advanced rectal cancer. Furthermore, blood plasma cytokine measurements before and after surgery will be compared to evaluate the effect of tumour resection on the immune response. In addition, preoperative blood plasma cytokine levels will be compared with cytokine levels in normal and tumour tissue to test whether circulating cytokine levels are representative for tissue cytokine levels.

Study burden and risks

For the patients included in the study there is no individual benefit. During this study 5 ml of blood from a selection of rectal cancer patients during a regular puncture before, during and after preoperative chemoradiotherapy and before and after surgery will be taken. At these time points regular blood samples are taken thus no extra puncture will be performed. No known risks are

associated with participation.

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

- Pathohistological diagnosis of locally advanced rectal adenocarcinoma (<15 cm from the anal verge)
- Eligible for preoperative chemoradiotherapy (chemotherapy: oral capecitabine/radiotherapy: 45-50 gray in total; fractions of 1.8-2 gray) and surgery (stage 2 or 3 rectal cancer)
- Planned to undergo a venapuncture for a regular blood collection during preoperative chemoradiotherapy, before, and after surgery
- Written informed consent

- Age *18

Exclusion criteria

- Age <18
- Serious adverse events during preoperative chemoradiotherapy
- Use of corticosteroids and/or immusuppressive drugs during or 1 month prior to the study
- Other malignancies in medical history
- Previous pelvic radiotherapy and/or chemotherapy
- Confirmed bacterial or viral infection during the study or 3 months prior to the study

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-02-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	13-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26782
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL46983.100.13
OMON	NL-OMON26782