Cytokines as predictors on response to preoperative chemoradiotherapy in patients with rectal cancer

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Cancer and cancer treatment result in an inflammatory response thereby cytokines are produced. Cytokines may also themselves influence therapy response. Various cytokines are abnormally expressed in colorectal cancer patients, are associated with...

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

Samenvatting

ID

NL-OMON26782

Bron
Nationaal Trial Register

Verkorte titel
CYTORECT

Aandoening

cytokines
predictive value
preoperative chemoradiotherapy
rectal cancer
predictieve waarde
preoperatieve chemoradiotherapie
rectumcarcinoom

Ondersteuning

Primaire sponsor: St Antonius Hospital
Overige ondersteuning: St. Antonius Oncology Centre
St. Antonius Research Fund (Crowdfunding)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Identifying cytokines which can predict response to preoperative chemoradiotherapy in patients with locally advanced rectal cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale and background: 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. Various cytokines are abnormally expressed in colorectal cancer patients, are associated with colorectal cancer or determine response to chemoradiotherapy. Therefore we want to investigate whether levels of circulating cytokines could predict response to preoperative chemoradiotherapy in patients with rectal cancer.

Hypothesis: Our hypothesis is that the varying levels of circulating cytokines in the blood of rectal cancer patients may predict the response to preoperative chemoradiotherapy.

Study design: This study is an explorative clinical pilot study in which we will collect 4 ml of blood from a selection of rectal cancer patients during a regular venipuncture before, during and after preoperative CRT and before and after surgery. 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 response to identify which cytokines and corresponding levels can predict response to preoperative CRT for 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 population: Thirty patients (≥18 years) with locally advanced rectal adenocarcinoma eligible for preoperative CRT (oral capecitabine and 45-50 gray (Gy) in total; fractions of 1.8-2 Gy) and surgery.

Country of recruitment: The Netherlands

Doel van het onderzoek

Cancer and cancer treatment result in an inflammatory response thereby cytokines are produced. Cytokines may also themselves influence therapy response. Various cytokines are abnormally 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.

Onderzoeksopzet

What: cytokine concentrations
Timepoints: 6 blood plasma measurements of cytokines per patient; specifically before, in week 3 and just after preoperative CRT, 1 day before and 2 days and 6 weeks after surgery. Tissue measurements of cytokines will be performed on the resection specimen.
How: multiplex immunoassays (LUMINEX)

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

St. Antonius Hospital
Koekoekslaan 1
Lotte Jacobs
Nieuwegein 3435 CM
The Netherlands
088 - 320 30 00

Wetenschappelijk

St. Antonius Hospital
Koekoekslaan 1
Lotte Jacobs
Nieuwegein 3435 CM
The Netherlands
088 - 320 30 00

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥18
- Pathohistological diagnosis of locally advanced rectal adenocarcinoma (<15 cm from the anal verge)
- Eligible for preoperative chemoradiotherapy (chemotherapy: oral capecitabine / radiotherapy: 45-50 Gy in total; fractions of 1.8-2 Gy) and surgery (stage 2 or 3 rectal cancer)
- Planned to undergo a venipuncture for a regular blood collection during preoperative CRT, before, and after surgery
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age <18
- Serious adverse events during preoperative chemoradiotherapy
- Use of corticosteroids and/or immunosuppressive 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	27-02-2014
Aantal proefpersonen:	30

Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37973
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4305
NTR-old	NTR4450
CCMO	NL46983.100.13
OMON	NL-OMON37973

Resultaten