Prospective validation of a predictive model for pathologic complete response after chemoradiotherapy in rectal cancer:
A prognostic study

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The long-term research objective is to be able to select rectum cancer patients who could receive a less invasive treatment. If prediction of response is possible, surgery may be avoided when complete response after chemoradiotherapy is expected or...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anal and rectal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON33076

Source
ToetsingOnline

Brief title
validation of a predictive model after complete response in rectal cancer

Condition

- Anal and rectal conditions NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
cancer of the rectum/rectumcancer

Research involving
Human

Sponsors and support

Primary sponsor: MAASTRO clinic
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: validation model chemoradiotherapy rectumcancer

Outcome measures

Primary outcome

Prediction of pathological complete response (ypT0N0) 8-12 weeks after

long-series chemoradiotherapy.

Secondary outcome

Several binary outcomes (assessed from pathology 8-12 weeks after long-series

chemoradiotherapy) are predicted for treatment adaptation:

1. TRG12 versus TRG34 (TRG: tumor regression grade, see Appendix F)

2. TRG1 versus TRG234

3. Percentage of ypT1-T2, N0

Study description

Background summary

Prediction of rectal tumor response after chemoradiotherapy (CRT) might be helpful in individualizing treatment strategies, i.e. selecting patients who need less invasive surgery or another radiotherapy strategy in stead of resection. For rectal cancer it is known that 10-30% of the patients will respond with a pathologic complete response (pCR) after CRT. From a retrospective study with multivariate analysis of both clinical and FDG-PET data, it was found that adding FDG-PET data collected before and after CRT leads to a more predictive model compared to evaluating only pretreatment clinical data. To validate this model, this registration study is proposed. Furthermore, it has been found that FDG-PET during treatment is very predictive for response and a more favorable time point to adapt treatment. Also, there

are indications that adding blood biomarkers to the data, results in higher accuracy for response prediction compared to clinical and imaging data alone. Therefore, FDG-PET during treatment and blood sampling are included in the protocol to improve the accuracy of the prediction models.

Study objective

The long-term research objective is to be able to select rectum cancer patients who could receive a less invasive treatment. If prediction of response is possible, surgery may be avoided when complete response after chemoradiotherapy is expected or performed with smaller incisions if stage reduction is significant. This support decision system helps to individualize patient treatment and can improve the quality of life for the patient.

Study design

28x radiotherapy. On day 15 of radiotherapy en 8 weeks after radiotherapy: 1 PET-CT scan
Before radiotherapie, on day 15 and 8 weeks after radiotherapy: blood sample taken.

Study burden and risks

Venapunction 2x (PET-CT) and 3x a blood sample will be taken, in total 1.5 hours of extra time.

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

• Histological proven rectal cancer
• UICC stage I-III
• Only primary tumors; no recurrences
• Willing and able to comply with the study prescriptions
• 18 years or older
• Have given written informed consent before patient registration
• No previous radiotherapy to the pelvis
• Only patients treated with concurrent chemoradiation

Exclusion criteria

• Not adenocarcinoma histology
• History of prior pelvis radiotherapy
• No contra-indication for PET-CT (claustrofobia/allergy)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-09-2009
Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	15-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-03-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL27852.068.09