MRI and PET in patients with locally advanced rectal cancer treated with preoperative radiochemotherapy.

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To evaluate the feasibility to assess treatment response on radiochemotherapy for locally advanced rectal cancer by repeated anatomical and functional MRI and FDG-PET.

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

Summary

ID

NL-OMON33842

Source
ToetsingOnline

Brief title
Imaging in rectal cancer

Condition

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

Synonym
rectal cancer, rectal carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MRI, PET, rectal cancer, response

Outcome measures

Primary outcome

Explorative study to determine the feasibility to apply anatomical and functional MRI and FDG-PET in the evaluation of treatment response after radiochemotherapy treatment for locally advanced rectal cancer compared to the pathological specimen as gold standard.

Secondary outcome

Determination of the most useful imaging variables and optimal timing sequence for the imaging modalities (diffusion weighted MRI, perfusion MRI and FDG-PET) to evaluate the tumour response on radiochemotherapy.

Study description

Background summary

For locally advanced rectal cancer the standard therapy is 5 weeks radiochemotherapy (RCT) followed by surgery 4-8 weeks afterwards. Surgery is performed independent of the response on RCT and is attended with substantial morbidity. In distal rectal tumours most patients need a colostomy. When a low anterior resection is performed faecal continence can be a serious problem. And other postoperative complications include urinary incontinence, pain in the anoperineal region and impaired bowel function or sexuality.
As shown in different studies there is an occurrence of a pathological complete respons (pCR) ranging from 12-24 % after standard preoperative RCT with capecitabine for locally advanced rectal cancer. A retrospective study Habr-Gama et al. reported that tumour resection could be omitted in patients with persisting clinical complete response (cCR) after 12 months. Surgical and non-surgical treatment groups had comparable overall and disease free survival and local recurrence rates. These findings indicate the possibility to perform RCT as sole treatment in patients with a good response. To discriminate patients with a good response from patients with a poor response, a tool is

needed to monitor the treatment response. FDG-PET and MRI alone both have been used to assess treatment response, but the accuracy of these methods alone is not sufficient to safely defer surgical treatment.

Study objective

To evaluate the feasibility to assess treatment response on radiochemotherapy for locally advanced rectal cancer by repeated anatomical and functional MRI and FDG-PET.

Study design

Explorative prospective diagnostic pilot study investigating the feasibility to use MRI and FDG-PET in the imaging before, during and after radiochemotherapy for response assessment on radiochemotherapy for locally advanced rectal cancer. Imaging response measurements will be compared with the pathological specimen as gold standard.

Study burden and risks

For study purposes the patients will undergo two extra MRI scans and two FDG-PET scans. The MRI scans will be performed with an intravenous contrast agent. These scans will be scheduled in combination with standard diagnostic scans, radiation treatment or standard follow-up appointments. The additional MRI scans will be performed during the third week of the radiochemotherapy and 4 weeks after the end of the pre-operative treatment. The additional FDG-PET scans will be performed before and in the third week of the treatment. The FDG-PET scans will be planned on the same day as and preceding the MRI scans. For the patients included in the study, there is no individual benefit, besides close clinical follow up. For each FDG-PET there is an irradiation load of 5-10 mSv, this is comparable with two CT scans and this involves moderate risk for the patient. However this irradiation load is negligible comapring to the irradiation treatment this irradiation load is delivered to the total body. Ttherefore we exclude patients from later studies involving irradiation except studies which patients directly benefit from.

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

Biopsy proven adenocarcinoma
Rectal tumor < 15 cm anal verge
T3-4N0-2M0: based on standard primary staging performed with MRI

Exclusion criteria

Patients who meet exclusion criteria for MRI at 3T
Patients who meet exclusion criteria for Gadolinium intravenous contrast (kidney function GFR < 60ml/min/1.73m2 or nephrogenic systemic fibrosis)
Patients with insulin dependent diabetes mellitus or blood plasma glucose concentration higher than 10 mmol/L
Patients with inflammable bowel disease or diverticulitis
Patients with history of pelvic surgery
Patients with history of pelvic tumours

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):	04-03-2010
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	08-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL20221.041.09