Repeated MRI to correlate rectal tumour motion to rectal wall motion: a feasibility study in order to develop a dose escalation strategy for rectal cancer

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To quantify rectal tumour motion using (cine-)MRI and to correlate this motion with rectal wall movement in order to check the feasibility for CBCT controlled dose escalation for rectal cancer.

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

Summary

ID

NL-OMON32591

Source
ToetsingOnline

Brief title
Repeated MRI to correlate rectal tumour and rectal wall motion.

Condition

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

Synonym
colorectal carcinoma, rectal cancer

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: Dose escalation, Image Guided Radiotherapy (IGRT), MRI, Rectal Cancer

Outcome measures

Primary outcome

Quantification of rectal tumour motion and correlation with rectal wall

movements using one (cine-)MRI in order to develop a CBCT controlled dose

escalation strategy for rectal cancer.

Secondary outcome

Not applicable

Study description

Background summary

For rectal cancer patients a clear association is known between the radiation dose delivered at the tumour, the response and the prognosis. However delivery of a high radiation dose is accompanied with high risk of adverse effects if healthy tissues can not be spared. Therefore optimal tumour localisation during radiotherapy (target verification) is an important issue. With standard x-ray portal image target verification there is insufficient soft tissue contrast to visualize pelvic soft tissue anatomy. Cone-beam computed tomography (CBCT) improves this with appropriate rectal wall visualisation, but still it is not possible to visualise the tumour and track tumour motion during therapy. Large irradiation fields are therefore needed to assure complete tumour irradiation. Consequentially healthy tissues are also irradiated which prevents delivery of very high dose because of the large adverse effects expected. Magnetic resonance imaging (MRI) provides excellent soft tissue contrast to visualise the tumour and rectal wall. Cinematic-MRI (cine-MRI) besides, offers the possibility to track real-time tumour motion to quantify tumour movement during a therapy fraction. From these (cine-)MRI data the relation between the rectal tumour motion and the rectal wall motion can be determined. When verifying the

rectal wall position using CBCT, this relation will estimate the tumour position. This is the first prerequisite for dose escalation using CBCT guidance.

Study objective

To quantify rectal tumour motion using (cine-)MRI and to correlate this motion with rectal wall movement in order to check the feasibility for CBCT controlled dose escalation for rectal cancer.

Study design

Observational study during short course pre-operative radiotherapy for rectal cancer with daily (cine-)MRI. One the first day of irradiation treatment a (cine-)MRI will be performed for quantification of tumour and rectal wall movement. On the second till the fifth day (cine-)MRI scans will be performed to validate the motion characteristics and correlations found in the first scan.

Study burden and risks

Patients will undergo daily (cine-)MRI scans. All scans will be scheduled in combination with radiation treatment, before or after the treatment fraction. The use of MRI is after proper screening free of any risks. For the patients included in the study there is no individual benefit.

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

Rectal tumour < 15cm from the anal verge
Receiving 5x5 Gy short course pre-operative radiotherapy
Written informed consent

Exclusion criteria

Patients who meet exclusion criteria for MRI following the protocol of the department of radiology UMC Utrecht
Patients with history of pelvic surgery
Patients with other pelvic malignancies
Patients with inflammable bowel diseases or diverticulitis

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):	04-10-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2009
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	NL29622.041.09