A Pilot Study to monitor changes in Rectum Carcinoma during Radiotherapy with multi-parametric MRI

Published: 05-08-2013
Last updated: 24-04-2024

This study aims to be a pilot study for the treatment of rectum carcinoma on the MRL. A dataset will be collected which allows for an estimation of the anatomical and geometrical variation of the GTV and of the variation of the functional response...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON38751

Source
ToetsingOnline

Brief title
changes in Rectum Carcinoma during Radiotherapy

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectum carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Research afdeling radiotherapie.

Intervention

Keyword: MRI, Radiotherapy, Rectum carcinoma

Outcome measures

Primary outcome

To establish an estimate on the anatomical variation (position, shape, size)

and functional MR parameters of the GTV during radiotherapy treatment.

Secondary outcome

Establish the feasibility of radiotherapy treatment planning for the treatment

of rectum carcinoma on an MRL.

Establish the need of adaptive replanning during the course of treatment on an

MRL

Study description

Background summary

An integrated MRI-linear accelerator (MRL) would be able to use Magnetic resonance imaging (MRI) images for pre-treatment setup of radiotherapy patients. While we have substantial information on the geometric changes in the clinical target volume (CTV) of rectum carcinoma patients using repeat-CT data, not much data is available on the (geometric and functional) behavior of the gross tumor volume (GTV) during treatment. Due to the excellent soft tissue contrast of Magnetic Resonance Imaging (MRI), and the possibilities of functional MRI, MRI exams during the course of treatment would make this information available. The MRL therefore opens up the possibility to reduce uncertainties in the shape and position of the GTV and to adapt the treatment to the functional response of the GTV to the treatment.

Study objective

This study aims to be a pilot study for the treatment of rectum carcinoma on the MRL. A dataset will be collected which allows for an estimation of the

anatomical and geometrical variation of the GTV and of the variation of the functional response of the GTV on the treatment. This knowledge is essentail for the investigation of the full potential of treating rectum carcinoma on the MRL. With the dataset a first estimate of the clinical opportunities of such treating can be derived, which would serve as the basis for further investigations.

The primary objective of the study is to establish an estimate of the anatomical variation (position, shape, size) and the functional MR parameters of the GTV during radiotherapy treatment.

Study design

The study is an observational pilot study in which 2 x 6 patients (6 male, 6 female) with proven adenocarcinoma in the rectum, receiving radiotherapy of 25 x 2 Gy will be included.
Each participating patient will receive weekly an additional MRI exam, before or after the radiotherapy fraction of that day.Resulting in a total 5 additional exams. The MRI exams will include a combination of anatomical and functional MRI scans (T1-Weighted, T2-Weighted, Diffusion-Weighted Imaging, Dynamic Contrast-Enhanced MRI).

Intervention

As part of this research there are five additional MRI scans. Because the first MRI scan made on the same day as the first radiation fraction it does not need a separate baseline MRI scan.

Study burden and risks

Patients undergo the standard MRI examination several times. In the standard exam, 15 ml of contrast DOTAREM (Gadoteric acid 0.5M) is administered i.v.. There are no side effects known of this agent. However, an allergic reaction can not be excluded. For patients who have undergone the standard examination as part of their treatment, the repetition of this exam presents a negligible risk.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX

NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with proven adenocarcinoma in the rectum, receiving radiotherapy of 25 x 2 Gy.

Exclusion criteria

- contra-indications for a MRI exam
- patients with prior irradiation or surgery in the pelvic area
- patients with WHO performance status more or the same as 2.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2013
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	05-08-2013
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL43563.031.13