A Feasibility Study of MR-based target delineation for Radiotherapy Treatment planning For Gastric Cancer

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Primary objective (part 1)* Establish the feasibility of MR-based target delineation for radiotherapy treatment planning for gastric cancer. Secondary objectives (part 2)* Assess the volumetric differences between clinical target volumes before and…

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

Summary

ID

NL-OMON43148

Source
ToetsingOnline

Brief title
MRI in gastric cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Gastric cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Geen geldstroom

Intervention

Keyword: Gastric cancer, MRI, Radiotherapy

Outcome measures

Primary outcome

Primary endpoints (part 1)

* Definition and delineation of the Clinical Target Volume (CTV) and

Organs-At-Risk

* Assessment of the time-averaged mid-position

Secondary outcome

Secondary endpoints (part 2)

* Volumetric differences between clinical target volumes before (first MRI) and

after (partial) gastrectomy (second MRI)

* Software tool for an MR-based target delineation for the treatment planning

of the stomach

* Definition and delineation of the Gross Tumour Volume (GTV)

Study description

Background summary

Studies have demonstrated that computed tomography (CT) based clinical target volume (CTV) delineations of gastric tumours have large variations (up to 19mm) between observers [1]. On top of that, the treatment area experiences much intra- and inter-fraction position variation due to oral intake, respiration and gas filling [2], leading to internal target volume (ITV) margins of 19.2, 13.5 and 7.8mm in respectively medio-lateral, cranio-caudal and antero-posterior directions. These uncertainties require generous treatment margins, increasing the radiation dose to normal organs and associated risk for toxicity. These factors are a serious limitation to the RT treatment.

MRI has superior soft-tissue contrast over (cone-beam) CT, facilitating CTV determination and detection of organ motion for gastric cancer [3,4]. Integration of MRI in the RT treatment chain, will therefore improve certainty with regards to the shape and position of the gross tumour volume (GTV) and the clinical tumour volume (CTV). This increase in certainty will likely lead to reduction of margins, potentially leading to a clinically significant reduction of toxicity. Furthermore, it is expected that functional MRI, will allow for the assessment of treatment response [5].

Study objective

Primary objective (part 1)
* Establish the feasibility of MR-based target delineation for radiotherapy treatment planning for gastric cancer.

Secondary objectives (part 2)
* Assess the volumetric differences between clinical target volumes before and after (partial) gastrectomy.
* Test and (if necessary) develop tools for an MR-based target delineation for the treatment planning of the stomach, such as software for registration, margin detection and mid-position determination.
* Evaluate the feasibility to delineate the macroscopic (gross) tumour volume.

Study design

Each patient will receive 2 additional MRI exams. The first exam will be scheduled before gastrectomy and, if applicable, before the start of any neo-adjuvant therapy. The second MRI will be scheduled 4 * 10 weeks after resection, but before any postoperative therapy. Both MRI exams will be used to create a planning dataset on which the clinical target volume (CTV), gross target volume (GTV, only on pre- operative MRI) and organs-at-risk (OARs) will be delineated. Both delineation sets will be compared volumetrically. The image quality will be evaluated, if it is feasible to delineate the clinical and gross tumour volume.

The study will be divided into two parts. In the first part, 5 patients will be included. Based on the data of these 5 patients, the feasibility of constructing a delineation from the acquired MRI-data will be assessed. The study is considered feasible when the clinical target volume (CTV) and the organs-at-risk (OARs) can be delineated, the data can be registered to each other and a reconstructed (mid-position) plannings scan can be assessed and can be used in treatment planning.

When this is considered feasible, an additional 15 patients will be included in part 2 of the study, resulting in a total of 20 patients.

Intervention

The patients will undergo MRI exams at two time points, before and after (partial) gastrectomy.
The scan duration of the first exam is approximately 50 minutes and the second scan will be less. The two MRI exams will not be used clinically.

Study burden and risks

Patients will undergo a MRI exam two additional times. During the MRI exam 15 ml of the contrast agent Dotarem (Gadoteric acid, concentration 0.5M) is administered intravenously. No adverse effects are known of the administration of a repeated dose one week after a previous exam. No risk has been reported of repeated MRI exams.

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

Patients with histologically proven gastric cancer, receiving a (partial) gastrectomy

Exclusion criteria

* Contra*indications for a MRI exam.
* Patients with prior irradiation or surgery in the gastric area.
* Patients with WHO performance status > 2.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-12-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	31-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	09-02-2017
Application type:	Amendment
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	NL57840.031.16