Repeated magnetic resonance imaging in esophageal cancer for adaptive radiation treatment planning during chemoradiotherapy.

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Primary objective:- To develop a patient-specific adaptive radiotherapy planning strategy using MRI with more precise target coverage and critical organ sparing by safely reducing treatment margins for resectable esophageal cancer irradiation....

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

Summary

ID

NL-OMON46841

Source
ToetsingOnline

Brief title
REACT

Condition

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

Synonym
esophageal cancer, oesophageal 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: Esophageal cancer, MRI, Radiotherapy

Outcome measures

Primary outcome

Observational study to analyse esophageal tumor regression and tumor movement during nCRT in order to develop adaptive radiotherapy planning strategies using intratreatment delineations of MR images to improve target coverage and critical organ sparing.

Secondary outcome

Only applicable to patients with resectable esophageal cancer:

Besides the primary endpoint anatomical and functional MR images will be used to further assess and evaluate the optimal time of scanning during nCRT to predict pathological response to treatment with pathology of the resected specimen as reference standard. Furthermore, the value of 'dynamic contrast-enhanced MRI' for early response assessment during nCRT will be assessed.

Study description

Background summary

The role of chemoradiotherapy (CRT) in the management of esophageal cancer is

growing. For resectable esophageal cancer, the standard therapy consists of 5 weeks of neoadjuvant chemoradiotherapy (nCRT) followed by surgery 6-8 weeks afterwards. The advantage of nCRT followed by a 6-8-week period before surgery is that this approach can induce significant tumor regression and downstaging, which leads to an increased rate of microscopically radical resections, decrease in local recurrences, a pathologic complete response (pCR) in 28-34% of the patients and an overall survival benefit. For unresectable esophageal cancer or inoperable patients due to comorbidities, definitive chemoradiotherapy (dCRT) is the treatment of choice. The current radiotherapy delivery to the esophageal tumor is not without adverse effect due to dose delivery to healthy tissues surrounding the tumor. Radiation pneumonitis, esophageal strictures, hearts failure, ischemic heart disease and postoperative pulmonary complications, such as anastomotic leakage, pneumonia or ARDS can directly be related to radiation dose delivered to these tissues.
Applying smaller irradiation margins may reduce short-term and long-term side effects. However safely reducing radiation fields is only justified when full tumor coverage is still assured. In order to develop more accurate radiation treatment plans with limited toxicity the shape of the radiation field needs to be adapted to the tumor. Therefore information about tumor shrinkage and movement during therapy is needed. We aim to study these changes with magnetic resonance imaging (MRI). This imaging modality has proven to provide excellent soft-tissue contrast and allows for non-invasive visualization of the tumor. Furthermore, a tool is desirable to accurately identify patients with good or poor response to nCRT. Functional MRI imaging during the first 2-3 weeks of nCRT has shown promising result in the prediction of pathological response. However, the optimal timing of scanning for pathological response prediction is unclear.
By visualizing both tumor shrinkage and movement during CRT and predicting pathological response to neoadjuvant treatment, a first step is made to safe adaptive radiotherapy planning strategies, using MRI. This development is expected to allow for more personalized treatment for patients with esophageal cancer.

Study objective

Primary objective:
- To develop a patient-specific adaptive radiotherapy planning strategy using MRI with more precise target coverage and critical organ sparing by safely reducing treatment margins for resectable esophageal cancer irradiation.

Secondary objective:(only applicable to patients with resectable esophageal cancer)
- To find the optimal timing for MRI guided response assessment to predict pathological response to nCRT as determined after surgery.
- Assessment of the value of 'dynamic contrast-enhanced MRI' for early response assessment during nCRT

Study design

Single-center prospective diagnostic study investigating the value of MRI in the imaging before and during CRT for esophageal cancer. The MRI protocol consists of anatomical MRI for the assessment of tumor movement characteristics and shrinkage, and functional MRI for treatment response assessment. Imaging response measurements will be compared with the pathological specimen as reference standard.

Study burden and risks

For study purposes patients will undergo six extra MRI scans. The use of MRI is negligible. Five scans will be scheduled in combination with radiation treatment and one scan will be scheduled in the first week prior to nCRT when the patient is in the hospital for radiation planning purposes. During the course of two MRI exams, an intravenous contrast agent is administered to the patient. This can lead to mild side effects of headache, nausea, injection site reaction, disturbed sense of taste and feeling hot. The use of the contrast agent has a very low risk (<1%) of an allergic reaction to the contrast medium.

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

- Histologically confirmed squamous-cell carcinoma, adenocarcinoma or large-cell undifferentiated carcinoma of the esophagus or esophagogastric junction (i.e. tumors involving both cardia and esophagus on endoscopy) - For nCRT: potentially resectable tumor (cT1b-4b N0-3 M0) and undergoing preoperative chemoradiation according to CROSS-regimen - For dCRT: unresectable tumor (T4bNxM0) or medically unfit patient for surgery due to comorbidities based on multidisciplinary consensus, undergoing definitive chemoradiation - Age>18 years - Signed informed consent

Exclusion criteria

- Patients who meet exclusion criteria for MRI following the protocol of the department of Radiology of the UMC Utrecht. -Patients who meet exclusion criteria for Gadovist gadolinium (Glomerular Filtration Rate (GFR) of <35 mL/min/1.73m2, *according to clinical protocol*). - Patients with a known Gadovist allergy - Patients having difficulty understanding Dutch - History of previous radiotherapy for thoracic, gastric or head and neck tumors - Pregnant or breast-feeding patients

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-12-2015

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-02-2018
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	NL53489.041.15