Feasibility of MRI in patients with esophageal tumors

Published: 15-04-2014
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The primary objective is to study the feasibility of MRI in patients with esophageal tumors. We will study its effectiveness for visualization of the cranial and caudal tumor borders and identification of the involved lymph nodes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47597

Source
ToetsingOnline

Brief title
Esophagus MRI

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Esophageal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Esophageal cancer, Lymph node, MRI, Tumor extension

Outcome measures

Primary outcome

The feasibility of MRI of esophageal cancer with emphasis on visualization of

1) the tumor extent in longitudinal direction and 2) the involved lymph nodes.

Secondary outcome

Niet van toepassing.

Study description

Background summary

Radiotherapy (RT) plays an important role in the treatment of esophageal cancer. RT is either applied as preoperative treatment for patients in an operable disease stage or as part of definitive treatment in inoperable cases. The challenge for RT in esophageal cancer is how to deliver the radiation accurately to the tumor and involved lymph nodes while minimizing normal tissue toxicity. The macroscopical disease extent is endoscopically determined by endoscopic ultrasonography (EUS). Difficulties arise in transfer of these endoscopic data to the computed tomography (CT) scan used for RT planning. Delineation of the tumor on CT is tedious due to the poor visibility of the tumor extension and lack of clear anatomical landmarks in distal direction of the esophagus. Due to uncertainties in the translation of the endoscopically identified disease extent to the CT scan used for RT planning, the uncertain extent of microscopic invasion, setup errors, and respiratory-induced movement during treatment generous safety margins of several cm are currently used leading to increased healthy tissue irradiation. If improved pre-treatment knowledge on the disease extent is available the accuracy of RT for esophageal cancer can be improved which will allow a reduction of the required safety margins and decrease the dose to organs at risk. This can most likely be achieved by improved imaging.

Study objective

The primary objective is to study the feasibility of MRI in patients with esophageal tumors. We will study its effectiveness for visualization of the

cranial and caudal tumor borders and identification of the involved lymph nodes.

Study design

The study is a prospective pilot study to test the feasibility of MRI in patients with esophageal tumors.

Patients who participate in this study will undergo a pre-treatment T2-weighted (T2w), diffusion weighted imaging (DWI) and dynamic contrast enhanced (DCE) MRI scan. Further, post-surgery the excision specimen will be imaged. Treatment protocols are based on routine clinical assessment and will not be altered based on the findings at MRI.

Study burden and risks

The burden is minimal: patients participating have to visit the hospital once to undergo MRI before the start of treatment. This visit will be scheduled on a day when the patient has already an appointment at the hospital. The MRI scan will take approximately 60 minutes. Further, gadolinium based contrast medium will be administered; therefore patients suffering from chronic renal insufficiency will be excluded. No additional side-effects or risks have been reported on MR imaging, although some patients may experience claustrophobia. Post-surgery the excision specimen will be imaged which is no burden to the patient.

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

1) Patients with histologically proven primary esophageal cancer for whom a surgical procedure (either with or without preoperatve CRT) is planned.
2) Referred for treatment in the AMC.
3) Written informed consent.
Further, at least fifteen out of the twenty-five patients referred for preoperative CRT should undergo pre-treatment EUS-guided radiopaque marker implantation.

Exclusion criteria

1) Contra indication for MRI.
2) Contra indication for gadolinium contrast administration.
3) Recurrent tumor after an esophageal resection.
4) Pregnant women.
5) Age < 18 years.
6) Unwilling to participate in the study and to sign informed consent.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-10-2014
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	15-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-08-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-12-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47713.018.14