Development of an MRI scanning protocol for functional imaging of esophageal cancer.

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Currently, only few publications exist which describe MRI for esophageal cancer. Therefore, the objective of the study is to develop a MRI protocol for imaging of this organ. The research will particularly be focussed on functional MRI. Those scans...

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

Summary

ID

NL-OMON44018

Source
ToetsingOnline

Brief title
Development of MRI for functional imaging of esophageal cancer.

Condition

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

Synonym
esophageal cancer, oesophageal 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: cancer, esophageal, MRI

Outcome measures

Primary outcome

Quality of the MRI images.

Secondary outcome

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Study description

Background summary

Esophageal cancer remains one of the most lethal cancers, despite the introduction of multimodality treatment (e.g. radiotherapy). The average 5-year survival is just 15-20%. Furthermore, the incidence of esophageal cancer has doubles over past 2 decades. Survival rates are low due to poor loco-regional control. It is expected that radiotherapy treatment can be improved by better visualization of the tumour. This way, irradiation can be better targeted to the tumour. It seems also relevant to identify patients with good response to radiotherapy. Some 30-50% of the patients are characterized as complete responders after surgery. For those patients, surgery may not be necessary. To improve tumour visualization and treatment response, MRI seems a promising technique. MRI is known for its good soft-tissue contrast. It was also shown that functional MRI techniques can useful to predict complete response of tumours after radiotherapy.

Study objective

Currently, only few publications exist which describe MRI for esophageal cancer. Therefore, the objective of the study is to develop a MRI protocol for imaging of this organ. The research will particularly be focussed on functional MRI. Those scans are suited for treatment response monitoring.

Study design

Observational study.

Study burden and risks

The patient will undergo an MR exam. No ionizing radiation is used to make an MRI scan; MRI scanning is a safe procedure. The MR exam lasts 45 minutes, the total time of the visit is expected to be an hour. To reduce the burden for the patient, we strive to plan the MR exam and other (conventional) exams or treatments on the same day. Each patient will be asked to undergo 2 or 3 MRI scans prior and/or during the course of radiotherapy.

Before the MR exam can take place, the glomerular filtration rate (GFR) needs to be known. If no recent value (< 3 months) is known, a venapunction is required. The majority of the patients, however, will have a recent GFR value available as it is required for conventional treatment planning (contrast-enhanced CT).

During the MR exam, an intravenous contrast agent is administered to the patient. This can lead to side effects: headache, nausea, injection side reaction, disturbed sense of taste and feeling hot. The use of the contrast agent has a very low risk of a 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

-Patients with pathologically proven esophageal cancer referred to the department of Radiotherapy for radiotherapy.
>18 years
-Written informed consent

Exclusion criteria

- Glomerular Filtration Rate (GFR) of <45 mL/min/1.73m2, unless the patient has risk factors for contrast nefropathy according to the UMCU protocol *Preventie contrastreactie en contrast nefropathie, Versie 2 februari 2012*. In patients with risk factors a GFR of 60 mL/min/1.73m2 will be required.
- Known Gadovist allergy.
- Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht

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):	01-03-2013
Enrollment:	30

Type:	Actual

Ethics review

Approved WMO Date:	23-01-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-08-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-11-2016
Application type:	Amendment
Review commission:	METC NedMec

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	NL42338.041.12

Register	ID
Other	TC3852