

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Malignant and unspecified neoplasms gastrointestinal NEC
<b>Study type</b>	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

### Public

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### Scientific

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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/1.73m<sup>2</sup>, unless the patient has risk factors for contrast nephropathy 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/1.73m<sup>2</sup> 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**

Other

**ID**

TC3852