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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29032

Source
Nationaal Trial Register

Health condition

esophageal cancer

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Quality of the MRI images as defined by robustness (i.e. that the protocol can successfully be applied in various patients) and geometrical accuracy. Those parameters are derived using image analysis. MR images are obtained before, during and/or after chemoradiotherapy.

Secondary outcome

N/A

Study description

Background summary

This study is aimed at optimizing a MR sequences for esophageal cancer imaging before, during and after chemoradiation. We will focus on diffusion-weighted imaging and dynamic contrast enhanced imaging. The obtained protocol will be used in future to verify if MRI can be used for treatment response monitoring of neo-adjuvant radiotherapy.

Study objective

A robust and geometrically correct MRI protocol can be developed that enables functional MR imaging before, during and after chemoradiation of esophageal cancer.

Study design

Before, during and after radiotherapy.

Intervention

None (patients undergo an MRI scan with contrast agent).

Contacts

Public
Heidelberglaan 100
A.L.H.M.W. Lier, van
Utrecht 3584 CX
The Netherlands
+31 (0)88 7558800
Scientific
Heidelberglaan 100
A.L.H.M.W. Lier, van
Utrecht 3584 CX
The Netherlands
+31 (0)88 7558800

Eligibility criteria

Inclusion criteria

1. Patients with pathologically proven esophageal cancer referred to the department of Radiotherapy for
radiotherapy;

2. >18 years;

3. Written informed consent.

Exclusion criteria

1. 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;

2. Known Gadovist allergy;

3. Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the UMC Utrecht.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	15-02-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion Date:	04-02-2013
Application type:	First submission

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
NTR-new	NL3682
NTR-old	NTR3852
Other	METC UMC Utrecht / CCMO Toetsingonline : 12/537 / NL42338.041.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A