Preoperative identification of response to neoadjuvant chemoradiotherapy for esophageal cancer.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24280

Source
NTR

Brief title
PRIOR

Health condition

Esophageal cancer.
MRI.
PET-CT.
Oesofaguscarcinoom.
Slokdarmkanker.

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

The additional diagnostic value -in terms of accuracy, sensitivity, specificity and predicitve values- of anatomical and functional MRI to PET-CT in the evaluation of treatment response to neoadjuvant chemoradiation therapy for patients with esophageal cancer, as compared to the pathological specimen as gold standard.

Secondary outcome

1. Assessment of the optimal (MRI and PET-CT) imaging parameters that correlate best with pathological response;

2. Assessment of the optimal timing for the imaging series;

3. Assessment of the diagnostic value of MRI for post-nCRT restaging of T- and N-stage as compared to histopathology;

4. Assessment of the experienced burden for the patient associated with extra MRI and PET-CT scanning in the clinical work-up for esophageal cancer, as determined by a self-administered questionnaire.

Study description

Background summary

N/A

Study objective

Anatomical and functional magnetic resonance imaging (MRI) are of additional value to combined 18F-fluorodeoxyglucose positron emission tomography and computed tomography (PET-CT) in the evaluation of treatment response to neoadjuvant chemoradiation therapy for patients with esophageal cancer.

Study design

1. Pre-chemoradiation: MRI and PET-CT;

2. 2 weeks after start of chemoradiation: MRI and PET-CT;

3. 1-2 weeks prior to surgery: MRI and PET-CT.

Intervention

1. Three MRI scans: Pre-, per- and post-chemoradiation therapy;

2. Three PET-CT scans: Pre-, per- and post-chemoradiation therapy.

Contacts

Public

[default]
The Netherlands
Scientific

[default]
The Netherlands

Eligibility criteria

Inclusion criteria

1. Histologically confirmed carcinoma of the esophagus or esophagogastric junction (i.e. tumors involving both cardia and esophagus on endoscopy);

2. Potentially resectable tumor (cT1b-4a N0-3 M0);

3. Undergoing neoadjuvant chemoradiation according to CROSS-regimen;

4. Age >18 years;

5. No history of other cancer or previous radiotherapy or chemotherapy;

6. Signed informed consent.

Exclusion criteria

1. Patients who meet exclusion criteria for MRI at 1.5T following the protocol of the Radiology department of the UMC Utrecht;

2. Glomerular Filtration Rate (GFR) of <45 mL/min/1.73m2, unless the patient has risk factors for contrast nefropathy according to the UMC Utrecht protocol ‘Preventie contrastreactie en contrast nefropathie, Versie 2 februari 2012’. In patients with risk factors a minimum GFR of 60 mL/min/1.73m2 will be required;

3. Patients with insulin dependent diabetes mellitus or a blood plasma glucose concentration higher than 10 mmol/L;

4. Patients with a known Gadovist allergy;

5. Patients with a known CT-contrast allergy;

6. Patients having difficulty understanding Dutch;

7. Pregnant or breast-feeding patients.

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):	01-07-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL3816
NTR-old	NTR3981
Other	CCMO : 42022.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A