Preoperative identification of response to neoadjuvant chemoradiotherapy for esophageal cancer

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

Summary

ID

NL-OMON39900

Source
ToetsingOnline

Brief title
PRIOR

Condition

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

Synonym
esophageal cancer, oesophageal carcinoma

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, PET-CT

Outcome measures

Primary outcome

- Exploration of the diagnostic value of anatomical and functional MRI and PET-CT in the evaluation of treatment response to nCRT for patients with esophageal cancer, as compared to the pathological specimen as gold standard.

Secondary outcome

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

- Assessment of the optimal timing for the imaging series.

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

- Assessment of the experienced burden for the patient associated with extra MRI and PET-CT scanning in the clinical work-up for esophageal cancer.

Study description

Background summary

Esophageal cancer remains one of the most lethal cancers, with an average 5-year survival of 15-20%. Furthermore, the incidence of esophageal cancer has doubled over the past two decades. For resectable esophageal cancer the standard therapy is 5 weeks of neoadjuvant chemoradiotherapy (nCRT) followed by surgery 6-8 weeks afterwards. Surgery is performed independent of the response to nCRT and is associated with substantial morbidity. A pathological complete response (pCR) after nCRT is seen in 28-34% of patients. Pathological non-responders (pNR) most probably do not benefit from nCRT but are exposed to its toxicity and delay from surgical therapy inevitably occurs in this group. Accurate identification of non-responders early during nCRT would allow

individualized decision making in continuation or discontinuation of nCRT. Furthermore, a tool is desirable to accurately assess the treatment response after nCRT to identify patients with a complete response. Studies in rectal cancer reported that tumor resection could be omitted in patients with persisting clinical complete response after 12 months. Also, in some esophageal cancer studies, complete responders in surgical and non-surgical treatment groups had comparable overall survival. These findings indicate the possibility to perform nCRT as sole treatment in patients with a complete response. On the contrary, if residual tumor is demonstrated, this will support the decision to move to surgery.

Study objective

The objective of this explorative study is to assess the value of anatomical and functional magnetic resonance imaging (MRI) and 18F-fluorodeoxyglucose positron emission tomography and computed tomography (PET-CT) in the evaluation of treatment response to nCRT for patients with esophageal cancer.

Study design

Single-center diagnostic pilot study investigating the value of MRI and PET-CT in the imaging before, during and after nCRT for assessment of response to nCRT for resectable esophageal cancer. Imaging response measurements will be compared with the pathological specimen as gold standard.

Study burden and risks

For study purposes the patients will undergo three MRI scans and two PET-CT scans in addition to the standard pre-nCRT PET-CT scan. MRI scanning is a safe procedure, no ionizing radiation is used. During the MRI exams, an intravenous contrast agent is administered to the patient. This can lead to mild side effects of headache, nausea, injection site reaction, disturbed sense of taste and feeling hot. The use of the contrast agent has a very low risk of an allergic reaction to the contrast medium.

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

Both the MRI and PET-CT scans will be scheduled in combination with standard diagnostic scans, radiation treatment or standard follow-up appointments. The scans will be performed before nCRT, after 2 weeks of the nCRT regimen and 5-7 weeks after the end of the preoperative treatment (1-2 weeks prior to surgery). The PET-CT scans will be planned on the same day as and preceding the MRI

scans. For the patients included in the study, there is no individual benefit. For each PET-CT there is an irradiation load of approximately 6.1 mSv, which involves moderate risk for the patient of developing a second malignancy. Therefore patients will be excluded from later studies involving additional irradiation unless patients directly benefit from these studies.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Histologically confirmed carcinoma of the esophagus or esophagogastric junction (i.e. tumors involving both cardia and esophagus on endoscopy)
- Potentially resectable tumor (cT1b-4a N0-3 M0)
- Undergoing neoadjuvant chemoradiation according to CROSS-regimen
- Age >18 years

- No history of other cancer or previous radiotherapy or chemotherapy
- Signed informed consent

Exclusion criteria

- Patients who meet exclusion criteria for MRI at 1.5T following the protocol of the Radiology department of the UMC Utrecht
- 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
- Patients with insulin dependent diabetes mellitus or a blood plasma glucose concentration higher than 10 mmol/L
- Patients with a known Gadovist allergy
- Patients with a known CT-contrast allergy
- Patients having difficulty understanding Dutch
- Pregnant or breast-feeding patients

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):	31-10-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	06-08-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL42022.041.13