Preoperative staging by combidex MRI in patients with resectable esophageal carcinoma

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	-

Summary

ID

NL-OMON28048

Source
NTR

Brief title
PRECIES study

Health condition

esophageal cancer

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

To assess the feasibility and diagnostic accuracy of nano-MRI in detecting locoregional lymph node metastases in patients with esophageal cancer whom underwent nCRT

Secondary outcome

- Diagnostic accuracy of the nano-MRI under anesthesia and controlled mechanical ventilation motion in detecting locoregional lymph node metastases in patients with esophageal cancer whom underwent nCRT

- Diagnostic accuracy of the nano-MRI in detecting locoregional lymph node metastases ex-vivo after nCRT

- Identify the effect of nCRT on the detection of lymph nodes metastases with nano-MRI

- Identify the quantitative effect of anesthesia and controlled mechanical ventilation motion MRI compared with ‘breathhold’ MRI.

- Compare the diagnostic accuracy of nano-MRI in detecting lymph node metastases with clinical staging results of esophageal cancer (CT, PET, EUS)

Study description

Background summary

In the Netherlands, more than 2000 patients are diagnosed with esophageal cancer. The curative treatment for resectable cancer consists of nCRT followed by surgical resection of the tumor as well as regional lymph nodes and is associated with severe mortality and morbidity and a substantial impact on quality of life. After nCRT, the percentage of patients with metastatic lymph nodes appears to reduce from 75% to 31% due to a pathological complete response. Accurate lymph node staging before surgery may reduce the number of unnecessary lymph node dissections and prevent morbidity. However, the sensitivity and specificity for determining lymph node metastasis is low to moderate for the imaging techniques used currently in the management of esophageal cancer. A promising new imaging technique for detecting lymph node metastases is nano-MRI. Nano-MRI uses small iron-dextran particles (USPIO), internalized by macrophages, to visualize positive nodes. nano-MRI is already proved in characterizing lymph nodes in patients with prostate cancer, with a high sensitivity and specificity of 65-92% and 93-98%. This imaging technique may bridge some of the limitations of existing imaging for nodal characterization in esophageal cancer and thereby may reduce the number of unnecessary lymph node dissections.

Study objective

We hypothesize that it is possible to detect lymph nodes metastases after neoadjuvant chemoradiotherapy (nCRT) prior to surgery with nano-MRI in patients with esophageal cancer. Better diagnosis may preclude unnecessary lymph node dissections, which still is the current standard. Patients who do not need a lymph node dissection due to the better

diagnostic accuracy will probably have less morbidity and a better quality of life.

Study design

-

Intervention

MRI scan with nano-contrast agent

Contacts

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Eligibility criteria

Inclusion criteria

• Patients with recently biopsy proven esophageal cancer, who are planned to undergo a esophagectomy with nCRT

• Patients with suspected lymph nodes metastases on EUS or CT before nCRT

• Age > 18 years

• Providing informed consent

Exclusion criteria

• Unable to provide informed consent

• Known pregnancy or breastfeeding

• Contra-indications for MRI

• Contra-indications for USPIO based contrast agents

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2016
Enrollment:	20
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-08-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43056
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5797
NTR-old	NTR6072
CCMO	NL58570.091.16
OMON	NL-OMON43056

Study results