Preoperative staging by combidex MRI in patients with resectable esophageal carcinoma

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To assess the feasibility of nano-MRI in the evaluation of locoregional lymph nodes metastases in patients with esophageal cancer whom underwent nCRT and to study the effect of nCRT on the detection of locoregional lymph nodes metastases with nano-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON43056

Source
ToetsingOnline

Brief title
PRECIES study

Condition

- Gastrointestinal therapeutic procedures

Synonym
esophageal cancer, esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: esophageal carcinoma, esophagectomy, lymph node metastases, nano-MRI

Outcome measures

Primary outcome

Evaluation of the feasibility and diagnostic accuracy of nano-MRI in detecting

locoregional lymph nodes metastases after nCRT prior to surgery

Secondary outcome

- Identify the quantitative and qualitative effect of controlled mechanical

ventilation motion compared with *breathhold* in detection of lymph node

metastases with nano-MRI after nCRT.

- Diagnostic accuracy of the nano-MRI in detecting metastases in locoregional

lymph nodes in the surgical specimen, ex-vivo after nCRT.

- Diagnostic accuracy of nano-MRI for staging primary esophageal cancer (CT,

PET, EUS).

Study description

Background summary

In the Netherlands, more than 2000 patients annually are diagnosed with esophageal cancer. The curative treatment for resectable cancer consists of neoadjuvant chemoradiotherapy (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 detecting lymph node metastases after nCRT is low to moderate for the imaging techniques used currently in the management of esophageal cancer. A promising new imaging technique for detecting lymph nodes is nano-MRI. Nano-MRI uses small iron-dextran particles (USPIO), internalized by macrophages, to visualize positive nodes. USPIO MRI is already proved in characterizing lymph nodes in patients with prostate cancer, with a high sensitivity of 65-92% and specificity of 93-98%.

Study objective

To assess the feasibility of nano-MRI in the evaluation of locoregional lymph nodes metastases in patients with esophageal cancer whom underwent nCRT and to study the effect of nCRT on the detection of locoregional lymph nodes metastases with nano-MRI

Study design

Single center exploratory study.

Study burden and risks

Included patients are already considered for nCRT followed by esophagectomy and will undergo an additional diagnostic MRI before nCRT and after nCRT prior to surgery (after induction of anesthesia) with intravenous injections of nano contrast agent. For this study, depending on other appointments, up to two extra visits to the Radboud university medical center are required. USPIO administration may cause (mild) side-effects in a small proportion of patients. Patients in this explorative study will not benefit from the extra diagnostic imaging. The results of this study are of high importance for the accurate re-staging of patients after nCRT. With accurate re-staging of the tumor, a less invasive surgical procedure without lymph node resection is possible in patients without viable tumor cells, preventing morbidity. Neoadjuvant therapy, surgical procedures and follow-up do not differ from regular practice.

Contacts

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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 histologically proven primary esophageal adenocarcinoma or squamous cell carcinoma, who are planned to undergo a esophagectomy after 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
- Epilepsy
- Metal implants that are not compatible with MRI
* Contra-indications for USPIO based contrast agents
- Prior allergic reaction to ferumoxtran-10 or any other iron preparation
- Prior allergic reaction contributed to dextran or other polysaccharide, in any preparation
- Prior allergic reaction to contrast media of any type
- Hereditary hemochromatosis, thalassemia, sickle cell anemia
- Inflammatory diseases of the abdomen

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-04-2017
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ferumoxtran-10
Generic name:	superparamagnetic iron oxide particles

Ethics review

Approved WMO Date:	09-11-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-07-2017
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28048
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-003133-18-NL
CCMO	NL58570.091.16
OMON	NL-OMON28048

Study results

Date completed:	19-09-2019
Actual enrolment:	16