

Preoperative staging by combidex MRI in patients with resectable esophageal carcinoma

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON28048

Bron

NTR

Verkorte titel

PRECIES study

Aandoening

esophageal cancer

Ondersteuning

Primaire sponsor: Radboudumc

Overige ondersteuning: Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

MRI scan with nano-contrast agent

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unable to provide informed consent
- Known pregnancy or breastfeeding
- Contra-indications for MRI
- Contra-indications for USPIO based contrast agents

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status: Werving gestopt

(Verwachte) startdatum: 01-10-2016

Aantal proefpersonen: 20

Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 05-08-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43056

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten