Pet ReInforced by MRI Enhancing detection of Residual Oesophageal cancer

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The hypothesis is that FDG-PET/MRI is more accurate than FDG-PET/CT for re-staging after nCRT.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28571

Source
NTR

Brief title
PRIMERO

Health condition

Locally advanced esophageal adenocarcinoma or squamous cell carcinoma

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC, departments of Surgery and Radiology & Nuclear Medicine

Intervention

Outcome measures

Primary outcome

The primary study parameter is qualitative re-staging after nCRT based on FDG-PET/MRI versus FDG-PET/CT, with pathology as gold standard (i.e. histopathologic assessment of the resection specimen when patients undergo surgery after nCRT, or histopathology/cytopathology of the primary tumor and suspected (distant) metastases as obtained during standard follow-up when patients do not undergo surgery or postpone surgery after nCRT).

Secondary outcome

Experienced burden of undergoing FDG-PET/MRI; quantitative measurements of the primary tumor and lymph nodes.

Study description

Background summary

FDG-PET/MRI is a new technique that combines simultaneous acquisition of an 18F-fluorodeoxyglucose positron emission tomography (FDG-PET) scan with a magnetic resonance imaging (MRI) scan. FDG-PET/MRI has the potential to provide better anatomical visualization compared to FDG-PET/computed tomography (FDG-PET/CT), which is the current standard functional imaging modality used for staging esophageal cancer. In addition, FDG-PET/MRI has the possibility to provide functional information through MRI-specific parameters that quantify cellular density in tissue, which has been shown relevant for tumor detection. However, the potential utility of FDG-PET/MRI for response evaluation after neoadjuvant chemoradiotherapy (nCRT) to facilitate and improve personalized treatment yet needs to be determined. The aim of the study is to evaluate the feasibility of FDG-PET/MRI to improve tumor response assessment after nCRT compared to standard FDG-PET/CT.

Study objective

The hypothesis is that FDG-PET/MRI is more accurate than FDG-PET/CT for re-staging after nCRT.

Study design

One time point, the extra study scan takes place at the response evaluation after nCRT.

Intervention

Patients receive treatment according to standard clinical care during the conduct of the study. Patients who participate in this study will undergo one FDG-PET/MRI scan in total, planned sequentially to a clinically indicated (preoperative) FDG-PET/CT after completion of nCRT.

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥18 years; - Histologically proven esophageal adenocarcinoma or squamous cell carcinoma located caudally to the carina; - Completed neoadjuvant chemoradiotherapy (nCRT); - Scheduled to undergo FDG-PET/CT at 4-6 weeks after nCRT or at 8-12 weeks after nCRT.

Exclusion criteria

- Contra-indications for MRI (e.g. pacemaker, metal implant, claustrophobia); - Contra-indications for iodinated contrast media (e.g. previous contrast-allergy or eGFR <30 ml/min/1,73m2); - FDG-non avid tumor as determined from the pre-treatment PET/CT scan; - Incapacitated patients, prohibiting the understanding and giving of informed consent and to complete the questionnaire on experienced burden with PET/MRI.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-07-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-03-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50029
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9352
CCMO	NL75204.078.20
OMON	NL-OMON50029

Study results