Pet ReInforced by MRI Enhancing detection of Residual Oesophageal cancer

Gepubliceerd: 19-03-2021 Laatst bijgewerkt: 02-12-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28571

Bron
NTR

Verkorte titel
PRIMERO

Aandoening

Locally advanced esophageal adenocarcinoma or squamous cell carcinoma

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC, departments of Surgery and Radiology & Nuclear Medicine

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	13-07-2021
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50029
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten