The predictive value of PET-CT and PET-DW-MRI early during chemoradiotherapy for head and neck cancer

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The last decade, radiotherapy with or without chemotherapy has become an organ spearing treatment modality for functionally irresectable head and neck squamous cell carcinoma (HNSCC) to retain the best quality of life. The early identification of...

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

Samenvatting

ID

NL-OMON28050

Bron
Nationaal Trial Register

Verkorte titel
PREDICTION

Ondersteuning

Primaire sponsor: Prof. dr. R. de Bree
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Overige ondersteuning: Initiator

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate the diagnostic value of FDG-PET-CT and DW-MRI (EPI and non-EPI technique) applied 2 weeks after the start of primary chemoradiotherapy for HNSCC to predict locoregional response in the primary tumor and cervical node metastases.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The last decade, radiotherapy with or without chemotherapy has become an organ spearing treatment modality for functionally irresectable head and neck squamous cell carcinoma (HNSCC) to retain the best quality of life. The early identification of non-responders to chemoradiation would spare a substantial number of patients from the morbidity of radiotherapy with or without chemotherapy and the increased risk of complications associated with salvage surgery. Moreover, this may lead to overall improvements in survival if radiotherapy can (still) be used, when indicated, as a post-operative modality.
Objectives: (1) To determine the diagnostic value of FDG-PET-CT and two diffusion-weighted MRI-techniques (EPI and non-EPI) performed pre-treatment and in the early phase of treatment in predicting the locoregional response to chemoradiation for HNSCC. (2) To determine the feasibility of PET-MRI in this population.

Study design: Prospective, single institute, observational study of 20 consecutive patients.

Study population: Patients with advanced technically resectable HNSCC scheduled for primary chemoradiation with curative intent.
Intervention: 2 FDG-PET-CT and 2 PET-DW-MRI scans (including diffusion-weighted images) prior to therapy and during therapy (2 weeks after the start of radiotherapy).
Main study parameters/endpoints: Criteria for predicting locoregional response and accuracy of FDG-PET-CT and DW-MRI (EPI and non-EPI technique). Feasibility of PET-MRI.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: In standard clinical practice these patients will undergo DW-MRI and FDG-PET-CT pretreatment for staging of the tumor. In this protocol, these patients will undergo one extra PET (part of pretreatment MRI), one extra FDG-PET-CT and one extra PET-DW-MRI extra (in the early phase of treatment) in context of the study. The DW-MRI will be made on the PET-MRI-scanner two hours after FDG-injection for PET-CT. A new PET will be made resulting in an extra 30 minutes scanning time. Radiation exposure due to repeated PET-CT scanning (10 mSv) is negligible compared to the radiation therapy of these patients. For PET-MRI no extra FDG will be administered.

These patients have no benefit of the extra FDG-PET-CT and PET-DW-MRI, as these scans are not used for clinical practice and treatment related decisions. In the future patients may

benefit from FDG-PET-CT and PET-DW-MRI during treatment in stopping futile (low chance to cure) chemoradiation and switch to surgical treatment with still some adjuvant radiotherapy available.

Doel van het onderzoek

The last decade, radiotherapy with or without chemotherapy has become an organ spearing treatment modality for functionally irresectable head and neck squamous cell carcinoma (HNSCC) to retain the best quality of life. The early identification of non-responders to chemoradiation would spare a substantial number of patients from the morbidity of radiotherapy with or without chemotherapy and the increased risk of complications associated with salvage surgery. Moreover, this may lead to overall improvements in survival if radiotherapy can (still) be used, when indicated, as a post-operative modality.

Onderzoeksopzet

Pretreatment: FDG-PET-CT and PET-DW-MRI
2 weeks after the start of radiotherapy: FDG-PET-CT and PET-DW-MRI

Onderzoeksproduct en/of interventie

Two FDG-PET-CT and two PET-DW-MRI scans (including diffusion-weighted images) prior to therapy and during therapy (2 weeks after the start of radiotherapy).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Squamous cell carcinoma

- Oral cavity, pharynx or larynx

- T2, T3 or T4

- Resectable (technically)

- Primary chemoradiation (with curative intent)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18 years

- Pregnancy

- Patients carrying a pacemaker, or unable to undergo an 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:	01-09-2013
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3946
NTR-old	NTR4111
Ander register	MEC : 2013/191
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten