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

No registrations found.

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

Summary

ID

NL-OMON28050

Source
Nationaal Trial Register

Brief title
PREDICTION

Sponsors and support

Primary sponsor: Prof. dr. R. de Bree
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Source(s) of monetary or material Support: Initiator

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To determine the value of different criteria, related to the primary objective, such as:

• FDG uptake level pretreatment (on PET-CT and PET-MRI)

• Residual FDG uptake level after 14 days of therapy (on PET-CT and PET-MRI)

• Change of FDG uptake (on PET-CT and PET-MRI)

• b=1000 signal intensity and ADC level pretreatment (for both EPI- and non-EPI-technique)

• Residual b=1000 signal intensity and ADC level after 14 days of therapy (for both EPI- and non-EPI-technique)

• Change of b=1000 signal intensity and ADC (for both EPI- and non-EPI-technique)
FDG-uptake levels obtained from PET-CT and PET-MRI will be compared (taking into account the different time intervals between FDG-injection and scanning)

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

- Squamous cell carcinoma

- Oral cavity, pharynx or larynx

- T2, T3 or T4

- Resectable (technically)

- Primary chemoradiation (with curative intent)

Exclusion criteria

- Age < 18 years

- Pregnancy

- Patients carrying a pacemaker, or unable to undergo an 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):	01-09-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3946

Register	ID
NTR-old	NTR4111
Other	MEC : 2013/191
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results