The predictive value of FDG-PET-CT early during (chemo-)radiotherapy for local control of advanced stage head and neck cancer

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To determine the diagnostic accuracy of FDG-PET-CT (pre-treatment and in the early phase of treatment) in the prediction of local control after primary radiotherapy with or without chemotherapy for functionally inoperable HNSCC.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON32415

Source
ToetsingOnline

Brief title
PETPRED study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
head and neck cancer, head and neck squamous cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: head and neck cancer, positron emission tomography, prediction of outcome, radiotherapy

Outcome measures

Primary outcome

Diagnostic accuracy of FDG-PET-CT applied 2 weeks after the start of primary

radiotherapy (with or without chemotherapy) for resectable HNSCC to predict

local failure in the primary and cervical node metastases.

Secondary outcome

* FDG uptake level pretreatment

* Residual FDG uptake level after 14 days of therapy

* Change of FDG uptake

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Study description

Background summary

The last decade, radiotherapy with or without chemotherapy has been an upcoming organ spearing treatment modality for functional inoperable head and neck squamous cell carcinoma (HNSCC) to retain the best quality of life. An early identification of nonresponders to (chemo)radiation would refrain a substantial number of patients from the morbidity and costs of a futile extensive treatment, the complications of salvage surgery and may improve survival due to the remaining option of postoperative radiotherapy.

Study objective

To determine the diagnostic accuracy of FDG-PET-CT (pre-treatment and in the early phase of treatment) in the prediction of local control after primary radiotherapy with or without chemotherapy for functionally inoperable HNSCC.

Study design

Prospective, single institute observational study of 20 consecutive patients.

Study burden and risks

In current clinical practice these patients undergo PET-CT pretreatment. In this protocol these patients will undergo one PET-CT extra (in the early phase of treatment) due to the study. Radiation exposure due to repeated PET-CT scanning (11 mSv) is negligible compared to the radiation therapy of these patients.
These patients have no benefit of the extra PET-CT, as this PET-CT is not reviewed until the end of the study. In the future patients may benefit from PET during treatment in stopping futile (low chance to cure) (chemo)radiation and switch to surgical treatment with still some adjuvant radiotherapy available.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with resectable advanced (stage III and IV) HNSCC scheduled for primary non-surgical treatment (radiotherapy with or without chemotherapy) with curative intent.

Exclusion criteria

technically inoperable tumor

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-01-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2007

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL20124.029.07