THE CLINICAL VALUE OF COMBINED FDG PET/CT IMAGING IN RESPONSE EVALUATION AFTER RADIOCHEMOTHERAPY IN PATIENTS WITH POTENTIALLY OPERABLE LOCALLY ADVANCED HEAD AND NECK SQUAMOUS CELL CARCINOMA

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To determine if FDG PET/CT is performant enough with respect to detecting residual lymph node involvement after chemoradiation in order to omit planned neck dissections in patients with locally advanced potentially operable, N2 and N3 head and neck...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON36288

Source
ToetsingOnline

Brief title
ECLYPS-study

Condition

- Respiratory and mediastinal 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: Agentschap voor Innovatie door Wetenschap en Technologie (Vlaanderen)

Intervention

Keyword: chemoradiotherapy, head and neck cancer, neck dissection, positron emssion tomography

Outcome measures

Primary outcome

The negative predictive value (NPV) of FDG PET/CT for detecting residual nodal

involvement

Secondary outcome

1. The sensitivity and specificity of high-resolution FDG PET/CT

2. The sensitivity and specificity of dual time point FDG PET/CT

3. The number of additional distant metastases found on PET and the % change in

patient management

4. DFS and OS, correlation with baseline SUV, early PET response and with HPV

status

Study description

Background summary

In patients treated with chemoradiation for a head and neck tumor, distinguishing between residual lymph node metastasis and radiotherapeutic induced tissue damage can be difficult. Expectative follow up runs the risk of treatment delay while a futile neck dissection induces morbidity and

costs.There is data to suggest that FDG-PET performed after completed chemoradiation has adequate diagnostic accuracy to improve the selection of patients for salvage neck dissection.

Study objective

To determine if FDG PET/CT is performant enough with respect to detecting residual lymph node involvement after chemoradiation in order to omit planned neck dissections in patients with locally advanced potentially operable, N2 and N3 head and neck squamous cell carcinoma (HNSCC).

Study design

All patients will undergo a dedicated PET/CT protocol 12 weeks after the end of chemoradiation (primary endpoint). In PET/CT negative patients, 2 monthly control visits will be performed complemented with additional imaging as required. All patients will undergo PET/CT 1 year after completing chemoradiation unless recurrent/residual disease was already proven pathologically. Patients with a PET/CT suspected for residual nodal disease must have pathological proof of nodal involvement (fine needle aspiration in non-operable patients or neck dissection in the others) before salvage surgery is started.
In a subset of patients receiving induction chemotherapy prior to concurrent chemoradiation, an additional PET scan will be performed at baseline and after 1 cycle of chemotherapy to evaluate the metabolic response to the treatment (secondary endpoint).

Study burden and risks

Burden for patients is 2 PET-CT scans. Risks are neglectable.

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

operable N2/N3 squamous cell carcinoma of head and neck
planned treatment of chemoradiation (with curative intent)

Exclusion criteria

Age < 18 years
Pregnancy
Physical condition contra-indication for neck dissection
Inoperable tumour in neck

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	14-02-2011
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	NL34141.029.10