

PET probe guided extirpation of FDG-PET positive lymph nodes which are negative on other imaging modalities in head and neck cancer patients scheduled for primary irradiation

Published: 24-02-2010

Last updated: 30-11-2024

Feasibility of PET probe guided extirpation of FDG-PET positive lymph nodes which are negative on other imaging modalities in head and neck cancer patients scheduled for primary irradiation.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON34841

Source

ToetsingOnline

Brief title

PET probe guided extirpation of FDG-PET positive lymph nodes

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: Ministerie van OC&W

Intervention

Keyword: extirpation, FDG-PET, lymph node metastases, PET-probe

Outcome measures

Primary outcome

Feasibility to extirpate these FDG-PET lymph nodes.

Secondary outcome

Diagnostic accuracy of PET-CT in these by other imaging techniques negative lymph nodes.

Chance of radiation planning.

Study description

Background summary

If all FDG-PET positive lymph nodes receive high dose irradiation the chance of overtreatment with potential side effects will be about 25%. If the other imaging modalities are negative the tumor load in the lymph nodes will probably be low, e.g. micrometastases. If these FDG-PET positive nodes can be identified, extirpated and investigated similar to the sentinel node biopsy procedure overtreatment can be avoided.

Study objective

Feasibility of PET probe guided extirpation of FDG-PET positive lymph nodes which are negative on other imaging modalities in head and neck cancer patients scheduled for primary irradiation.

Study design

Prospective, observational pilot study of 20 patients.

Intervention

FDG-PET/CT

Lymph node extirpation under general anesthesia guided by PET-probe

Study burden and risks

In current clinical practice these patients will receive high dose radiation on FDG-PET positive lymph node of which it is not clear if this lymph node contains metastatic cells. If the nature of this FDG positive lymph node is clear, a correct radiation dose can be given, avoiding futile radiation to normal tissue which may decrease toxicity.

The exposure to radioactivity by FDG will be low compared to the radiation treatment. The lymph node extirpation will be performed by a head and neck surgeon experienced with the sentinel node biopsy in the head and neck. In the literature on head and neck cancer no serious adverse events have been reported using these techniques. Lymph node extirpation will be performed under general anaesthesia.

Contacts

Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117

1081 HV

NL

Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117

1081 HV

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients with a primary biopsy proven head and neck cancer scheduled for primary irradiation with or without chemotherapy
- Lymph nodes which are positive on FDG-PET but negative on other imaging modalities
- Ultrasound guided fine needle aspiration cytology of these FDG-PET positive lymph nodes remains negative if performed after the results. This procedure must be performed afterwards if FDG-PET reveals these unexpected FDG-PET positive lymph nodes.
- FDG-PET positive lymph nodes have impact on radiation treatment planning if based on FDG-PET as judged by the radiation oncologist.
- *Informed consent* signed by patient

Exclusion criteria

none

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Will not start

Start date (anticipated): 01-12-2009

Enrollment: 20

Type: Anticipated

Ethics review

Approved WMO

Date: 24-02-2010

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	NL30458.029.09