

Lymphoscintigraphy in head and neck patients treated with primary radiotherapy

Published: 11-02-2008

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To analyze the change in lymphatic mapping in HNSCC patients treated by primary radiation therapy on the primary tumor and neck.

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

Summary

ID

NL-OMON31486

Source

ToetsingOnline

Brief title

SNERT 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: Ministerie van OC&W

Intervention

Keyword: head and neck cancer, lymphoscintigraphy, radiotherapy

Outcome measures

Primary outcome

Alteration of lymphatic drainage after primary radiation therapy.

Secondary outcome

none

Study description

Background summary

Treatment of lymph nodes is based on the knowledge that the pattern of metastatic spread is predictable, and related to site, size and histopathological status of the primary tumor. However, any disturbance of normal drainage by radiotherapy can result in other pathways of lymphatic drainage with dissemination of cancer cells. Lymphoscintigraphy is able to supply a complete map of the lymphatic drainage and thereby tailoring treatment which may minimise the extent of under- and overtreatment.

Study objective

To analyze the change in lymphatic mapping in HNSCC patients treated by primary radiation therapy on the primary tumor and neck.

Study design

This is an observational non-randomized single-institute pilot study.

Study burden and risks

Lymphoscintigraphy is a procedure which is used routinely in other tumor types. In the literature on head and neck cancer no serious adverse events have been reported using these techniques.

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 squamous cell carcinoma of the head and neck

Scheduled for primary irradiation of the primary tumor and neck

Primary tumor accessible for peritumoral injection of radiolabeled colloid

No clinical lymph node metastases pretreatment

No previous neck pathology or treatment to the primary tumor or neck (surgery, radiotherapy or chemotherapy) that may alter lymphatic drainage

Exclusion criteria

age < 18 or > 80 years

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): 05-05-2008

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 11-02-2008

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

CCMO

ID

NL21087.029.07