Mapping of Sentinel lymph node drainage Using SPECT to tailor highly-selective elective nodal irradiation in node-negative neck of patients with head and neck cancer (SUSPECT)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42014

Source
ToetsingOnline

Brief title
SN-SPECT for tailoring elective nodal irradiation

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head and Neck Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: de eigen afdeling icm Nucleaire Geneeskunde

Intervention

Keyword: Head and Neck Cancer, Radiotherapy, SPECT/CT

Outcome measures

Primary outcome

Feasibility and safety as well as regional control, toxicity and quality of

life of this approach will be investigated

Secondary outcome

NA

Study description

Background summary

Although considerable gains have been achieved over the last few decades with regard to loco-regional control (LRC) and overall survival (OS) in patients with head and neck cancer (HNC), the incidence of radiation-related toxic¬ity remains high, obviously because of the radiation damage to the salivary glands, mucosal area, swallowing and chewing muscles and structures involved in voicing and articulation. Despite the introduction of new highly-conformal radiation techniques the rate of these side effects remains high, mostly because of the large irradiated volumes, for instance because of bilateral neck irradiation.

This study aims to explore the feasibility, safety and outcome of a non-invasive sentinel node mapping (SNM) to individually tailor the elective nodal irradiation (ENI) to the ipsilateral neck only and to exclude the contralateral negative neck from the irradiation fields when there is no draining sentinel node. Subsequently the dose to the salivary glands, mucosal area and the swallowing and chewing muscles and structures involved in voicing and articulation will significantly be reduced.

Study objective

The aim of the study is to investigate the feasibility, safety, toxicity, quality of life (QoL), and regional control of unilateral ENI using SNM with SPECT/CT to select patients with unilateral drainage in lateralized HNSCC treated with primary radiotherapy or chemoradiation.

Study design

This study will be a single center phase II study. The duration of the study will be 36 months, with an inclusion rate of at least 1 patient per month. Each patient has a follow-up for 5 years (standard of care)

Intervention

SPECT/CT scan. Injection of Technetium-99m-nanocolloid (as a radioactive tracer) will be performed during the routine endoscopy under general anesthesia

Study burden and risks

In patients participating in the study, radioactive Tc-Albumin (Nanocolloid), as radioactiver tracer, will be injected submucosally around the tumor. Subsequently, SPECT/CT will be performed to identify the draining lymph nodes in order to tailor the neck levels to be treated electively, trying to exclude the elective irradiation of the contralateral clinically negative neck. The use of SPECT/CT for the SNM will tailor the ENI to highly selective levels when unilateral drainage is present. This approach has, therefore, the potential to reduce the radiation dose to different organs at risk, such as salivary glands, mucosal area and the swallowing and chewing muscles and the structures involved in voicing and articulation and subsequently the incidence of different troublesome radiation-induced side effects such as xerostomia, dysphagia and trismus, significantly affecting patients* quality of life. The radiation burden is estimated at 0,8 mSv from the radiopharmaceutical (0,01 mSv/MBq) and 1 mSv from low dose CT of the neck, for a total of about 2 mSv for the complete procedure. This is in the range of routine clinical diagnostic procedures. Allergic reactions or other adverse reactions have not been described. There will be no additional invasive procedures. Thus, the procedure is considered safe and well-tolerable by the selected patient group.

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

* Newly diagnosed patients with histopathologic proven primary HNSCC (T1-3N0-2b with maximally 3 involved nodes without extranodal spread) located in the oral cavity, oropharynx, larynx (except T1 glottic), and hypopharynx, not crossing the midline and planned for treatment with (chemo)radiotherapy in curative setting
* No chemotherapy or surgery prior to inclusion
* No distant metastatic spread
* Age * 18 years
* WHO performance status 0 or 1
* Signed written informed consent

Exclusion criteria

* Patients with previously radiation treatment in the head and neck region, for any reason.
* Patients with previous neck dissection.
* Patients with recurrent or second primary tumor in the head and neck region
* Patients with head and neck malignancies arising from skin, lip, nose, sinuses, nasopharynx, salivary glands, thyroid gland or esophagus.

* Previous history of cancer in the last 5 years (excluding basal cell carcinoma of the skin and in situ SCC of the cervix)
* Pregnancy or no active contraception for pre-menopausal women
* Known hypersensitivity to iodine or nanocolloid injection
* Having any condition (physical, mental, sociological) that interferes with the informed consent procedure and follow-up schedules

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	14-04-2015
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	09-12-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	10-12-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
ClinicalTrials.gov	NCT02572661
CCMO	NL51706.031.14