Mapping of Sentinel lymph node drainage Using SPECT/CT to tailor highly selective elective nodal irradiation in node-negative neck of patients with head and neck cancer - SUSPECT-2

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To prospectively evaluate the oncologic safety of selective SPECT/CT-guided ENI in a larger cohort of HNSCC patients

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

Summary

ID

NL-OMON54554

Source
ToetsingOnline

Brief title
SUSPECT-2

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: Eigen afdeling

Intervention

Keyword: Head and Neck cancer, Radiotherapy

Outcome measures

Primary outcome

Cumulative incidence of contralateral regional metastasis at 1 year after

treatment

Secondary outcome

Toxicity

Quality of Life

Prevalence of metastatic disease in contralateral sentinel nodes removed based

on lymph drainage mapping using SPECT/CT at baseline

Study description

Background summary

Most patients with head and neck squamous cell carcinoma (HNSCC) receive electively nodal irradiation (ENI) to both sides of the neck in order to reduce the risk of contralateral regional failure (cRF). However, there is increasing evidence that the incidence of cRF in lateralized HNSCC is very low (<10%). Bilateral ENI, as compared to unilateral ENI, is associated with higher incidence of acute and late radiation-induced toxicity with subsequent deterioration of quality-of-life (QoL). One way to reduce the incidence, duration and severity of these toxicities is by implementation of unilateral ENI, in patients where this can be justified.
The first SUSPECT study (N14SUS) investigated whether lymph drainage mapping (LDM) using Single Photon Emission Computed Tomography/Computed Tomography (SPECT/CT) was a safe and feasible method to exclude the contralateral neck from irradiation, or, in case of contralateral lymph drainage, to tailor the

contralateral ENI field to the level containing the tracer accumulation (*hot spot*). Large dose reductions to most organs at risk were realized, as well as significant reductions of both short term (mucositis, dysphagia) and long term (xerostomia, dysphagia) toxicities (to be published).
The SUSPECT-2 study aims to further reduce the proportion of patients that undergoes conventional bilateral ENI, by performing a contralateral sentinel node procedure (SNP) in case of contralateral lymph drainage; and to expand the inclusion criteria of the SUSPECT-1 study.

Study objective

To prospectively evaluate the oncologic safety of selective SPECT/CT-guided ENI in a larger cohort of HNSCC patients

Study design

Prospective multicentre phase II trial

Intervention

Injection of radioactive tracer submucosally around and in the tumor; subsequently lymph drainage mapping using SPECT/CT and contralateral sentinel node procedure (in case of contralateral lymph drainage). Unilateral or bilateral elective nodal irradiation based on results SPECT/CT and sentinel node procedure.

Study burden and risks

Subjects in this study will undergo a lymph drainage mapping using SPECT/CT, which will have the advantage of sparing about 80% of the patients from contralateral elective nodal irradiation altogether. The remaining 20% will undergo removal of the contralateral sentinel node by means of a minimally invasive procedure, but the majority of those patients will need no further treatment of the contralateral neck, instead of being treated with contralateral ENI and risking its associated short and long term toxicity.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
AMSTERDAM 1066CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Newly diagnosed and histopathologically proven lateralized primary HNSCC, T1-4N0-2b without midline involvement, originating at one side of the oral cavity, oropharynx, larynx (except T1 glottic), and hypopharynx, and planned for treatment with primary radiotherapy, chemo-radiotherapy or immuno-radiotherapy in curative setting
• Age >= 18 years
• WHO performance status 0 or 1
• Signed written informed consent

Exclusion criteria

• Distant metastatic spread at the time of inclusion
• Chemotherapy or surgery (for the present tumor), prior to inclusion
• Previous radiation treatment in the head and neck region, for any reason
• Previous neck dissection
• Recurrent or second primary tumor in the head and neck region
• Head and neck malignancies arising from skin, lip, nose, sinuses, nasopharynx, salivary glands, thyroid gland or esophagus
• 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:	Recruiting
Start date (anticipated):	22-07-2019
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-02-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL68958.031.19