Reduction of complications for head and neck cancer: Individual lymph node irradiation (iNode)

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

Summary

ID

NL-OMON51653

Source
ToetsingOnline

Brief title
iNode

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
Head and neck cancer / tumor

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Lymph Nodes, Magnetic Resonance Imaging (MRI), Radiotherapy, Squamous Cell Carcinoma of Head and Neck

Outcome measures

Primary outcome

The percentage of fractions successfully performed on the MR-Linac. Either inadequate patient tolerability or planning/contouring issues could lead to missing fractions.

Secondary outcome

Regarding patient safety:

• Regional recurrence occurring inside the elective neck volumes

• MR-related hearing impairment, measured in the first weeks after RT treatment

Regarding RT toxicity:

• Quality of life scoring: EORTC Quality of Life Questionnaire (QLQ-C30) and the EORTC Quality of Life Questionnaire HNC cancer (QLQ-HN35). Patients will be invited to fill out questionnaires at baseline and 3, 6, 12 and 24 months after treatment.

• Common Terminology Criteria for Adverse Events (CTCAE) will be filled in by the radiation oncologist before the start of RT and 3, 6, 12 and 24 months after treatment.

Regarding patient tolerability:

• Patient reported outcomes (PROs) regarding tolerability of treatment on the MR-linac will be measured with the previously validated MRL patient reported experience questionnaire of the PERCEIVE study (METC-protocol number: 20-624/C)

on three time points: after the first, the 10th and the last fraction.

Study description

Background summary

Radiotherapy applied for head and neck cancer causes long-term complications in many patients. A recent study showed 48% of all patients still have swallowing complaints 8 years after radiotherapy treatment. A dry mouth was still apparent in 66% of all patients. 23-53% of all patients had dysfunction of the thyroid. And, in 29% of all patients carotid stenosis was observed with possible vascular brain injury. Radiotherapy treatment for these patients consists of a high dose to the primary tumor and visible regional metastasis, and a lower dose to the lymph node levels. The lower dose that serves as treatment of possible non-visible regional lymph node metastases, plays an important role in the occurrence of long-term complications. With MRI non-suspect lymph nodes possibly containing metastasis are better visualized. Accordingly, non-suspect lymph nodes could be irradiated instead of the larger lymph node levels in which the nodes are located in. A more precise way of applying irradiation to treat occult metastasis could cause a decrease in long-term complications.

Study objective

In the iNode project we want to show it is technically possible to irradiate individual lymph nodes. For this reason, we will treat 20 patients with laryngeal, hypopharyngeal or oropharyngeal cancer with radiation. The radiation dose will be applied to the individual lymph nodes instead of the larger lymph node levels. The treatment will be administered with the MR-linac, a combination of a MRI-scanner and a radiation device that was developed in the UMC Utrecht. We consider the study procedures clinical acceptable if on average 16 out of 20 fractions could be performed on the MR-Linac.

Study design

This is a monocenter phase I feasibility study, that will be performed in the UMC-Utrecht.

Intervention

In this study individual lymph nodes will be irradiated with the full elective dose, the lymph node levels possibly containing small invisible lymph nodes will be irradiated with a lower dose. In this way the risk of regional recurrence will remain low.

Study burden and risks

Patients in the iNode study will receive a lower dose to the elective neck volumes compared to conventional treatment. Based on the results of our planning study, we expect a substantial reduction of dose in the carotid arteries, thyroid and submandibular glands. These dose reductions could lower RT related toxicity. The risk of RR might be higher, since the dose applied to the elective neck volumes is lower. However, based on our dose calculations for occult metastases we do not expect a higher RR.
The treatment time on the MR-linac will be approximately twice as long compared to conventional treatment (15 vs 30-60 min). If patients cannot endure treatment on the MR-linac it is still possible to finish treatment on the conventional linac. Switching to conventional treatment will not have consequences for the treatment
outcome.
Hearing protection is provided in compliance with standard procedures, and hearing loss is therefore not expected to occur as a result of the noise exposure caused by the MR. However, there is little experience with repetitive MR noise exposure in a time span of several weeks as is encountered in the RT schedules of 35 fractions on the MR-linac. There is only one retrospective cohort study describing similar exposure, in which no clinical relevant hearing loss was concluded (Bongers et al., 2017). To ascertain that there is no permanent hearing damage after the repetitive exposure to the MR noise, hearing loss will be closely monitored by an audiologist.

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

- Squamous cell carcinoma of the larynx, oropharynx or hypopharynx
- T2 -T4 stage
- N0-1, based on bilateral ultrasound / MRI / PET of the neck
- Indication for curative primary (accelerated) RT
- Indication for bilateral ENI

Exclusion criteria

- Concurrent chemotherapy or cetuximab
- Patients unsuited for MRI imaging
- Synchronous malignant tumor(s) at another site
- Previous malignancies in the HN region treated with surgery, chemotherapy or radiotherapy, except for tumors treated with endoscopic glottic laser microsurgery.
- Previous dissection of LNs in the neck
- A history of malignant disease for which treatment was ended < 2 year before diagnosis of the HNSCC, except basal cell carcinoma
- Age <18 years
- WHO performance status: >= 2
- Distant metastasis
- Participation into another interventional study
- Mental or physical impairment causing the participant to be unable to fill out questionnaires

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	22-06-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	28-12-2022
Application type:	Amendment
Review commission:	METC NedMec (Utrecht)

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	NL79278.041.22