Validation of diffusion weighted MR images of laryngeal cancer with histopathology

Published: 15-03-2016
Last updated: 19-04-2024

To compare the volume of the tumour as determined using DW-MRI images of laryngeal and hypopharyngeal tumours with that of the actual tumour as determined using histopathology after laryngectomy. Further, histopathology will be used to determine the...

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

Summary

ID

NL-OMON55866

Source
ToetsingOnline

Brief title
CORRECT II

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
laryngeal cancer, Laryngeal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Imaging, Laryngeal cancer, MRI, Pathology

Outcome measures

Primary outcome

The accuracy of DW-MRI in determining the volume of the tumour.

Secondary outcome

The sensitivity (part of the tumour that is delineated) and positive predictive power (part of the delineated volume that is tumour) of DW-MRI based tumour delineation compared with values obtained using CT, PET and anatomical MR imaging.

The microscopic extension of the tumour measured as the distance between the gross tumour volume and the most distant microscopic lesions in the histopathology.

Study description

Background summary

Irradiation of the larynx and the hypopharynx using modern radiotherapy techniques leads to favourable cure rates at the expense of a relatively large number of severe (15%) and mild complications (40%). These complications are caused by the irradiation of healthy tissues. The volume of healthy tissue exposed to a high dose of radiation can be reduced since in imaging validation studies it has been observed that the tumour volume is overestimated using current imaging techniques.
The hypothesis of this study is that the tumour volume can be determined accurately using a newly developed diffusion weighted magnetic resonance imaging contrast (DW-MRI). Reduction of the target volume for radiation therapy will reduce the number of complications and decrease the severity of

complications.

Study objective

To compare the volume of the tumour as determined using DW-MRI images of laryngeal and hypopharyngeal tumours with that of the actual tumour as determined using histopathology after laryngectomy. Further, histopathology will be used to determine the exact location, extent and the microscopical extension of the tumour in the surrounding tissue.

Study design

This study is a descriptive, diagnostic study that will evaluate DW-MRI images for tumour delineation in laryngeal and hypopharyngeal cancer.

Study burden and risks

In the normal clinical procedure patients will undergo a magnetic resonance imaging (MRI) scan, a computed tomography (CT) scan with iodine contrast and a Fluor-18-Fluorodeoxyglucose positron emission tomography (FDG-PET) scan. As part of standard care, all the imaging procedures before the total laryngectomy will be performed in a radiotherapy mask.
If standard clinical imaging is not available, too old (>20 days prior to surgery) or of insufficient quality for study purposes, participants will undergo an extra FDG-PET/CT and/or MRI. This ensures that all participants receive FDG-PET/CT and MRI prior to treatment. However, most participants will receive clinical imaging, therefore, no study burden to the participant due to imaging is expected. If additional FDG-PET/CT is needed, participants will be exposed to extra radiation due to study participation.
In the days before surgery patients are hospitalized and consequently no extra visits to the hospital will generally be required.

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 a T3 or T4 laryngeal or hypopharyngeal cancer scheduled for total laryngectomy.
- Age >= 18 years.
- Informed consent.

Exclusion criteria

- Patients with indications for primary radiotherapy.
- Patients with contraindications for surgery.
- Patients who meet exclusion criteria for MRI at 3T as defined in the protocols of the Radiology department.
- Patients with contraindication for CT contrast administration as defined in the protocols of the Radiology department.
- Patients with insulin dependent diabetes mellitus.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	15-03-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-07-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-02-2021
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	NL53576.041.15