Image validation of laryngeal and hypopharyngeal cancer with histopathology for radiotherapy.

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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-OMON33702

Source
ToetsingOnline

Brief title
volume and localisation validation of laryngeal cancer

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
larygeal cancer, larynx carcinoma

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: imaging, laryngeal cancer, pathology, tumour volume

Outcome measures

Primary outcome

The accuracy of the different image modalities to measure the tumour volume and outline as determined by comparison with histopathology as reference standard.

Secondary outcome

· assessment of microscopic invasion of the tumour in the surrounding tissue by histopathology.

· determination of the interobserver variation for tumour delineation using the different image modalities.

· feasibility of diffusion weighted imaging for laryngeal and hypopharyngeal cancer.

· development of a clinical imaging protocol for gross tumour volume (GTV) and clinical tumour volume (CTV) delineation.

Study description

Background summary

Irradiation of the larynx and the hypopharynx using modern fractionation schedules leads to favourable cure rates at the expense of a relatively large number of severe (15%) and mild complications (40%). Currently, radiation treatment of the larynx consists of high dose irradiation of the complete

larynx without delineation of the tumour volume. This is caused by the lack of information on the extent of the tumour. The hypothesis of the study is that the tumour volume can be determined by a combination of MRI, DCE-CT and FDG-PET and that smaller target volumes will be delineated if a combination of these image modalities is used. Reduction of the target volume for radiation therapy will reduce the number and decrease the severity of complications.

Study objective

The accuracy of the different imaging modalities will be assessed with histopathology as the reference. Further, histopathology will be used to estimate the microscopic extension of the tumour in the surrounding tissue. The topological correspondence is defined as the conformity index: 2* volume_overlap_region/(volume_regio1 + volume_regio2)

Study design

This study is a descriptive, diagnostic study, that will evaluate DCE-CT, FDG-PET and MRI for tumour delineation in laryngeal and hypopharyngeal cancer. To account for interobserver variations, the tumour volume will be delineated independently by two observers in all the image modalities. The overlap between the delineated GTVs of both observers as calculated for the different image modalities will be presented as a conformity index. Further, the interobserver overlap will also be described as a conformity index.

Study burden and risks

Apart from the normal clinical imaging procedure, all patients will undergo a DCE-CT with a higher dose than the normal multi slice CT. Moreover, all imaging procedures will be performed in a mask before the total laryngectomy, which may be burdensome for the patient. This enables the use of the presurgery images to define the target volume in the routinely performed postsurgery radiotherapy, that might improve target volume definition and minimize radiation dose to normal structures. In the days before surgery, patients are hospitalized and, therefore, generally no extra visits to the hospital will be required. Because of the extensive histopathological procedure, the pathological diagnosis will be available several days later than normally. This will not delay the adjuvant radiotherapy treatment of the patient.

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 of the above population scheduled for total laryngectomy.
Informed consent

Exclusion criteria

Patients with indications for primary radiotherapy.
Patients with contraindications for surgery.
Patients who meet exclusion criteria for MRI at 1.5 T 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.
no informed consent.

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):	28-05-2010
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	09-02-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (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	NL24342.041.09