Clinical value of (improved) 3 Tesla and 7 Tesla MR Imaging on depiction of T1 laryngeal carcinoma

Published: 03-11-2014
Last updated: 20-04-2024

The purpose of this study is to assess the feasibility of the clinical use of 3T MR imaging for early glottic carcinoma.

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

Summary

ID

NL-OMON42195

Source
ToetsingOnline

Brief title
3T and 7T larynx study/LOCATE

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
cancer of the vocal cord, laryngeal 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: 3 Tesla, laryngeal carcinoma, MRI

Outcome measures

Primary outcome

To assess the feasibility of the clinical use of 3T MR imaging of early laryngeal carcinoma;

- Systematic assessment of technical image quality and assessment of tumour visibility on 3T MRI.

- Anteroposterior tumour extension, lateral tumour extension (measured from free edge of the vocal fold in mm), estimated tumour infiltration depth (mm) and estimated tumour volume (cc) after delineation of the tumour at 3T MRI by an experienced head and neck radiologist.

- Anteroposterior tumour extension and lateral tumour extension (measured from free edge of the vocal fold in mm) during direct suspension laryngoscopy (reference standard).

- Tumour infiltration depth (in mm and invasion of tissue layer: superficial lamina propria, epithelium, Reinke*s space, vocal ligament, vocalis muscle) on structured histopathologic examination.

- Anteroposterior tumour extension, lateral tumour extension (mm), infiltration depth (mm) and estimated tumour volume (cc) on Computed Tomography, after delineation of the tumour by an experienced head and neck radiologist.

Secondary outcome

Not applicable

Study description

Background summary

CO2 endoscopic laser surgery and radiotherapy are the main treatment modalities for early glottic carcinoma (Tis and T1a/b). Regarding the national guideline 'Larynxcarcinoom' (NWHHT) CO2 endoscopic cordectomy is indicated for superficial T1a midcord lesions. When the AC is involved, the contralateral vocal cord is affected (T1b), or T1a lesions extend into the deeper layers of the lamina propria or vocal muscle, CO2 laser surgery is expected to result in worse functional outcome, and therefore radiotherapy in advocated. Up to now, endoscopic evaluation under general anaesthesia is the reference standard to assess tumour extension. CT is routinely performed to evaluate subglottic or paraglottic and extralaryngeal extension. However, vizualisation of small primary tumours may be difficult. The lack of information on the extent of the tumour might lead to an underestimation of the extent of tumour with or without AC involvement, resulting in unfavourable treatment. MR imaging is not regularly performed in early glottic carcinoma, but a small pilot study shows promising results. A renewed imaging protocol of 3 Tesla MRI is expected to be of complementary value for detection of tumour extension in early glottic carcinoma.

Study objective

The purpose of this study is to assess the feasibility of the clinical use of 3T MR imaging for early glottic carcinoma.

Study design

Prospective, non-randomized, feasibility study

Study burden and risks

Additional to routine staging protocol, 3T MRI will be scheduled. 3T MRI and gadolinium based contrast are considered safe. MRI's will be scheduled in combination with a regular appointment, if feasible.
To minimize the risk of movement artefacts and optimize image quality, a mask that covers the region from the chin to the shoulders is prepared for each patient. This mask is similar to the 5-point stabilization mask used for head and neck radiotherapy, but not covering the face, minimizing patient discomfort.

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 primary clinical Tis, T1a and T1b glottic carcinoma, scheduled for treatment with CO2 laser therapy or radiotherapy
- Capablility of written informed consent
- Written informed consent

Exclusion criteria

- Patients with a history of previous glottic surgery
- Patients with recurrence of glottic disease
- Legal incapability
- Insufficient command of the Dutch language

- Patients with body implants, not compatible with MRI
- Patients with Claustrofobia
- Pregnant patients
- Creatinine clearance of <50mL/min/1.73m²
- Known allergy for Gadovist or Iodinated contrast

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):	17-12-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	03-11-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	15-02-2016
Application type:	Amendment
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	NL48196.041.14