Detection of recurrent head and neck tumours after chemoradiation with a tumor-sensitive MRI technique.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29514

Source
NTR

Brief title
RETURNED

Health condition

squamous cell carcinoma, recurrence, radiotherapy
plaveiselcelcarcinoom, recidief, radiotherapie

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU), Department if ENT
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The diagnostic performance of DW-MRI for the detection of recurrence in patients with clinical suspicion of recurrent or persistent HNSCC after initial (chemo) radiation will be primarily

reflected by the PPV of DW-MRI. Furthermore, the NPV, discrimination, sensitivity and specificity will be assessed.

Secondary outcome

1. Number of futile biopsies with DW-MRI as selection strategy for endoscopy with taking of biopsies;

2. Discordant pairs (Regular imaging vs. DW-MRI);

3. Number of missed cases by DW-MRI compared to regular imaging;

4. Number of extra cases detected by DW-MRI compared to regular imaging.

Study description

Background summary

This study will investigate the accuracy of DW-MRI in detection of recurrent oropharyngeal, hypopharyngeal and laryngeal squamous cell carcinoma after (chemo)radiation.

Study objective

Diffusion Weighted MRI is an accurate imaging technique for detection of recurrent head and neck squamous cell carcinomas after (chemo)radiation therapy.

Study design

T0 = When there is a clinical suspicion of a recurrence;

T1 = 6 months post DW-MRI.

Intervention

One additional Diffusion Weighted MRI added to the regular imaging of choice.

Contacts

Public
W. Grolman
Dept. of Otolaryngology

Room G05.129
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88 75 566 44
Scientific
W. Grolman
Dept. of Otolaryngology
Room G05.129
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88 75 566 44

Eligibility criteria

Inclusion criteria

1. Patients with a oropharyngeal, hypopharyngeal, or laryngeal squamous cell carcinoma treated with (chemo)radiation with curative intent;

2. A clinical suspicion of a recurrence;

3. Last radiotherapy: > 2 months and < 3 years ago;

4. ‘Informed consent’ signed by patient;

5. Age ≥ 18 years.

Exclusion criteria

1. Patients with contraindication for MRI or contrast agent;

2. Patients who received salvage surgery for the primary lesion;

3. Patients whom recurrence is so obvious that no additional imaging confirmation is necessary for the decision to take biopsies.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-12-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35371
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3024
NTR-old	NTR3172
CCMO	NL37889.041.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35371

Study results

Summary results
N/A