Detection of recurrent head and neck squamous cell carcinomas with DW-MRI after (chemo)radiation

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To study the diagnostic capacity of DW-MRI for detecting recurrence in patients with suspicion of recurrent or persistent HNSCC after initial (chemo)radiation. This study aims to enhance early, low cost detection of recurrence and avoid futile...

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-OMON35371

Source
ToetsingOnline

Brief title
DW-MRI in HNSCC after (chemo)radiation

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
hypopharyngeal and oropharyngeal carcinoma, laryngeal, oral and throat cancer

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: Diffusion weigthed MRI, Head and neck, Oncology, Recurrent

Outcome measures

Primary outcome

The outcome of the study is the presence or absence of histological validated recurrent HNSCC within 6 months after the suspicion. 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 as reflected by the positive predictive value, negative predictive value, sensitivity and specificity of DW-MRI.

Secondary outcome

Secondary endpoints are the number of futile biopsy procedures if DW-MRI would be used as selection strategy and the extra yield by DW-MRI; the number of patients with a histological proven recurrence whereby DW-MRI was positive and regular imaging was negative. In addition the missed recurrences with DW-MRI; the number of patients with histological recurrence within 6 months whereby the DW-MRI was negative.

Study description

Background summary

Post-radiation changes make diagnosis of recurrent or persistent head and neck squamous cell carcinomas (HNSCC) after (chemo)radiation challenging. Imaging modalities such as CT and conventional MRI often have difficulties discriminating between post-radiation changes and tumour recurrence. Metabolic imaging such as FDG-PET has additional value, but limitations due to low spatial resolution and false-positive results caused by inflammatory disease

remain. Recent studies have shown that diffusion weighted MRI (DW-MRI) could be an imaging modality with promising capacity in differentiating between recurrence and post-radiation changes. Increased differentiation might lead to a reduction of futile biopsies with need of an endoscopy under general anaesthesia. Moreover, DW-MRI might allow early diagnosis of recurrence.

Study objective

To study the diagnostic capacity of DW-MRI for detecting recurrence in patients with suspicion of recurrent or persistent HNSCC after initial (chemo)radiation. This study aims to enhance early, low cost detection of recurrence and avoid futile biopsies with need for general anaesthesia.

Study design

A prospectively designed diagnostic study to evaluate the diagnostic capacities of DW-MRI in patients with suspicion of recurrent or persistent HNSCC. All consecutive patients suspected of recurrent or persistent HNSCC in the UMC Utrecht will receive a DW-MRI added to the regular imaging. If either the regular imaging or the DW-MRI is suggestive for recurrence, biopsy will follow for histological confirmation. If the regular imaging and DW-MRI are both negative, patients remain in expectative follow up as in the regular protocol. Reference standard is presence or absence of a histological proven recurrence within 6 months after the suspicion.

Study burden and risks

Apart from regular imaging modality (CT, MRI or FDG-PET scan) patients will undergo DW-MRI. No relevant risks associated with MRI for patients without contra-indication and a normal renal function have been reported. The DW-MRI will be scheduled so that the patient can combine a visit to the hospital for clinical and study purposes.
Only in patients who have negative regular imaging and positive DW-MRI , the diagnostic protocol will differ from the regular protocol. They will undergo endoscopy with taking of a biopsy as they normally would not. These patients might benefit if conventional imaging is false-negative and DW-MRI is true-positive (since studies on DW-MRI reported higher sensitivity and specificity than conventional imaging). However, the DW-MRI might also be false-postive. In that case, the patient undergoes unnecessary endoscopy with taking of a biopsy with risks such as infection, bleeding and the risk of general anaesthesia. However, these are very rare complications.

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 clinical suspicion of local recurrence after treated for laryngeal-hypopharyngeal- or oropharyngeal squamous cell carcinoma with (chemo)radiation.
Primary (chemo)radiation for the primary tumour region
Last radiotherapy: > 2 months and < 3 years
Informed consent signed by patient
Age * 18 years

Exclusion criteria

Patient with contraindication of MRI or contrast agent as defined in the protocols of the radiology department of the UMCU

Patients with primary salvage surgery for the primary lesion
Patients whom recurrence is obvious that no additional imaging confirmation is necessary for the decision to take biopsies.

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):	05-12-2011
Enrollment:	74
Type:	Actual

Ethics review

Approved WMO

Date:	17-11-2011
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

ID: 29514
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37889.041.11
OMON	NL-OMON29514