Detection of distant metastases in head and neck cancer patients by whole body FDG-PET and whole body MRI

Published: 20-07-2009
Last updated: 04-05-2024

To study the value of whole body MRI in screening on distant metastases in HNSCC patients with high risk factors.

Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Observational non invasive

Summary

ID

NL-OMON32960

Source
ToetsingOnline

Brief title
Detection of distant metastases by whole body MRI

Condition

- Metastases

Synonym
distant metastases; head and neck cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: distant metastases, FDG-PET, head and neck cancer, whole body MRI

Outcome measures

Primary outcome

Primary endpoints are the proportion of clinically relevant findings (detection

of distant metastases) with MRI and/or PET/CT and the diagnostic accuracy of

MRI, PET/CT and combination of MRI and PET/CT.

Secondary outcome

Secondary endpoint is the interobserver agreement of MRI and PET/CT.

Study description

Background summary

The detection of distant metastases in head and neck squamous cell carcinoma (HNSCC) patients can avoid futile extensive treatments. In routine clinical practice HNSCC patients with high risk factors for distant metastases undergo pretreatment screening on distant metastases by FDG-PET/CT. However, follow-up reveals that a substantial percentage of distant metastases are missed. Therefore, room for improvement remains. Due to the introduction of multi-receiver channel MR, whole body MRI (WB-MRI) has become clinically feasible and shows promising results for the detection of distant metastases in other solid tumours.

Study objective

To study the value of whole body MRI in screening on distant metastases in HNSCC patients with high risk factors.

Study design

This is a prospective observational non-randomized single-institute pilot study of 20 consecutive patients.
All patients will undergo pretreatment whole body FDG-PET/CT and whole body MRI in random order as dictated by logistics.

accuracy of both diagnostic techniques will be determined and compared.

Study burden and risks

In current clinical practice these patients undergo FDG-PET/CT pretreatment. Whole body MRI may potentially detect additional distant metastases. Radiation exposure of PET/CT is very low as compared to the radiation therapy which almost all of these patients will undergo. In this study no adverse or serious adverse events are expected, since FDG-PET/CT and MRI scans are used in common daily practice for this indication. Patients may benefit, because futile extensive treatments will be avoided if any distant metastases are detected.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

head and neck cancer
high risk factors for distant metastases
candidate for extensive locoregional treatment with curative intent

Exclusion criteria

known with distant metastases (no screening)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL27603.029.09