Whole-body MR imaging for staging malignant lymphomas in adults

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The aim of this study is to examine if WB-MRI can replace CT in staging of patients with a malignant lymphoma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas NEC
Study type	Observational non invasive

Summary

ID

NL-OMON31806

Source
ToetsingOnline

Brief title
WB-MRI lymphomas adults

Condition

- Lymphomas NEC
- Lymphomas NEC

Synonym
lymph node cancer, Malignant lymphomas

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,ZONMW (aangevraagd)

Intervention

Keyword: Hodgkin, non-Hodgkin, staging, Whole-body MR imaging

Outcome measures

Primary outcome

The challenge of this study will be to show non-inferiority of WB-MRI compared to CT in staging malignant lymphoma (according to the Ann Arbor classification). Testing of this hypothesis will be one-sided and performed using recently

proposed techniques by Lui et al. [Lui KJ, et al. Testing non-inferiority (and equivalence) between two diagnostic procedures in paired-sample ordinal data. Stat Med 2004;23:545-59].

Secondary outcome

Image quality DWIBS-scan at different magnetic field strengths:

Average apparent contrast-to-noise ratio's with corresponding standard deviations of DWIBS0-images obtained in 20 of 110 patients at 1.0 T, 1.5 T, and 3.0 T will be compared

Radiation-related risk assessment (CT-scan):

A risk model will be used, based on the BEIR VII report, for modelling the late-term mortality from radiation induced tumors after exposure to ionizing radiation [Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2, Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation, National Research Council, 2006, ISBN: 030909156X].

Economic evaluation:

Actual costs (from a societal perspective) will be determined for the two diagnostic tests. In case of clinical equivalence and similar costs or cost savings associated with MRI the latter can be considered dominant, obviating further economic evaluation. Otherwise, through modelling of expected long term health impact and associated outcomes such as quality of life and costs the incremental cost effectiveness will be evaluated.

Study description

Background summary

The malignant lymphomas, Hodgkin*s disease (HD) and non-Hodgkin*s lymphoma (NHL), comprise approximately 5-6% of all malignancies in adults and account for 10% of childhood cancers. Once the diagnosis has been established histologically, extent of disease (staging) and response to therapy will be assessed by means of a computed tomography (CT) scan of the body. The staging at presentation is important for determining prognosis and choice of treatment. Unfortunately, CT is accompanied by a significant amount of radiation exposure which may induce second cancers. Moreover, the intravenous application of a contrast agent necessary for CT can cause allergic reactions and may cause contrastnephropathy. New magnetic resonance imaging (MRI) techniques offer an alternative way for staging and follow-up of cancers, including the malignant lymphomas. Whole-body MRI (WB-MRI), including diffusion-weighted sequences (DWIBS), is a radiation-free method which allows imaging of the body with excellent soft tissue contrast in a single examination, without the application of a contrast agent.

Study objective

The aim of this study is to examine if WB-MRI can replace CT in staging of patients with a malignant lymphoma.

Study design

This will be a unicenter, prospective, diagnostic cohort study (timeschedule: 36 months). 110 eligible patients will undergo WB-MRI on top of the protocollar imaging routinely done.

For optimalization of the DWIBS-sequence, 20 of 110 included patients will also undergo a DWIBS-scan (i.e. only a DWIBS-scan, no conventional whole-body MRI) on another MRI-scanner, respectively 10 at 1.0 T and 10 at 3.0 T.

Study burden and risks

The patient has to lie in the MRI-scanner for approximately 45 minuten. 20 of 110 included patients will undergo an extra MRI-scan in another MRI-scanner, which will take approximately 20-25 minutes. All MRI-scans are completely non-invasive and without any adverse side-effects.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- male or female patients
- age: 18 years and older
- histologically proven Hodgkin's disease or non-Hodgkin's lymphoma
- patients scheduled for a CT of the body for initial staging and follow-up
- the participant must willingly give written informed consent prior to the start of the study
- Whole-body MRI has to be performed within 10 days before or after CT, and before therapy has been started.

Exclusion criteria

- patients with a general contraindication for MRI (including cardiovascular pacemakers, claustrofobia)
- patients who have had a previous malignancy
- patients who are pregnant or nursing
- patients in whom therapy has already started after CT and before MRI could be performed

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2008
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	03-07-2007
Application type:	First submission
Approved WMO Date:	14-08-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-10-2008
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	NL16857.041.07