Whole-body MRI for initial staging, early response assessment and restaging after completion of therapy in pediatric Hodgkin lymphoma.

Published: 20-05-2011
Last updated: 04-05-2024

The aims of this study are to compare the diagnostic performance of whole-body MRI (including DWIBS) to FDG-PET/CT and/or CT for the initial staging, early response assessment and restaging after completion of therapy in children with Hodgkin*s...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lymphomas Hodgkin's disease
Study type	Observational invasive

Summary

ID

NL-OMON41368

Source
ToetsingOnline

Brief title
Whole-body MRI in pediatric Hodgkin lymphoma

Condition

- Lymphomas Hodgkin's disease
- Lymphomas Hodgkin's disease

Synonym
Hodgkin lymphoma, lymph node cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hodgkin lymphoma, restaging, staging, Whole-body MRI

Outcome measures

Primary outcome

The primary outcome will be the clinical stage according to whole-body MRI/DWIBS findings and according to FDG-PET/CT and/or CT-findings. This clinical stage will be determined according to the Ann Arbor classification system for initial staging and according to the Cheson criteria for early response assessment and restaging. The interobserver variability of the MRI assessment will be evaluated.

Secondary outcome

The secondary outcome will be a (subjective) assessment of image quality and presence of artefacts, for T1-weighted, T2-weighted and DWIBS MR images as well as FDG-PET/CT and/or CT.

Furthermore, following the initial staging MRI and FDG-PET/CT examinations, patients will be asked to complete a short questionnaire to evaluate the perception of burden of undergoing MRI and FDG-PET/CT.

Study description

Background summary

The malignant lymphomas, Hodgkin*s lymphoma (HL) and non-Hodgkin*s lymphoma

(NHL), comprise approximately 10% of childhood cancers. The assessment of extent of disease (staging) and response to therapy (restaging) is performed with 18F-fluorodeoxyglucose positron emission tomography (FDG-PET scan), computed tomography (CT) scan or integrated FDG-PET/CT. Staging and restaging are important for choice of treatment and for determining prognosis. Unfortunately, FDG-PET and CT are accompanied by a significant amount of radiation exposure which may induce second cancers. New magnetic resonance imaging (MRI) techniques offer an alternative way for staging and follow-up of cancers. Whole-body MRI with diffusion weighted imaging (WB-MRI with DWIBS) is a radiation-free method which allows imaging of the body with excellent soft tissue contrast in a single examination and could be an attractive alternative to FDG-PET and CT for the initial staging, response assessment and restaging of malignant lymphomas in children.

Study objective

The aims of this study are to compare the diagnostic performance of whole-body MRI (including DWIBS) to FDG-PET/CT and/or CT for the initial staging, early response assessment and restaging after completion of therapy in children with Hodgkin*s lymphoma.

Study design

Patients eligible for enrollment in this multicenter, prospective, diagnostic cohort study are children aged 8-18 years, with histologically confirmed Hodgkin lymphoma, who are treated according to the SKION / Euronet-PHL-C1 protocol in one of the participating centers. Patients will undergo WB-MRI on top of the protocollar imaging routinely done (FDG-PET(/CT) scan and CT) at 3 time-points: at initial staging, after 2 chemotherapy cycles and at end of treatment. We expect to enrol 75 patients in a 3 year study period. Staging and restaging results of WB-MRI (according to the Ann Arbor and Cheson classification, respectively) will be compared to those of FDG-PET(/CT) and CT. All imaging modalities will be assessed by a radiologist and nuclear medicine physician in a blinded fashion, using standardized score forms. Findings of FDG-PET and CT together will serve as the reference standard. Clinical and radiological follow-up after 6 months will be used to solve any disagreements between FDG-PET, CT and WB-MRI. Furthermore, clinical and radiological 3-year follow-up data will be obtained from hospital charts of the patients, to enable better evaluation of the prognostic value of MRI and FDG-PET on recurrence of disease.

Study burden and risks

The patient has to lie in the MRI-scanner fo approximately 50 minutes. This MRI-scan is completely non-invasive and has no adverse side-effects.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- male or female patients
- age: 8-18 years
- histologically proven Hodgkin's disease
- enrolled in the EuroNet-PHL-C1 trial
- patients scheduled for a FDG-PET/CT or CT of the body for initial staging, early response assessment or restaging at end of treatment
- the participant must willingly give written informed consent prior to the start of the study and before each MRI
- Whole-body MRI has to be performed within 15 days before or after FDG-PET/CT or 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 FDG-PET/CT and before MRI could be performed
-Apparent signs of resistance

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):	18-04-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	20-05-2011
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-08-2012
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	07-02-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-11-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL34472.041.10