

# Whole-body MR imaging for staging malignant lymphomas in children

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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.

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

## Summary

### ID

NL-OMON31205

### Source

ToetsingOnline

### Brief title

WB-MRI lymphomas children

### 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

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. This is especially important in childhood, because rapidly dividing cells are more sensitive to radiation induced effects and children will have more years ahead in which cancerous changes might occur. 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). 15 eligible patients will undergo WB-MRI on top of the protocollar imaging routinely done.

### Study burden and risks

The patient has to lie in the MRI-scanner for approximately 45 minutes. This MRI-scan is completely non-invasive and has no adverse side-effects.

## Contacts

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## 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: 8-17 years
- 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
- Apparent signs of resistance

## 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): 14-02-2008

Enrollment: 15

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)

## 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	NL16860.041.07