# screening for coronary disease after mediastinal irradiation in Hodgkin Lymphoma survivors

Published: 24-11-2010
Last updated: 02-05-2024

Primary objectives:1: To determine whether CT- coronary angiography by MSCT as a screening method of HL survivors treated with mediastinal irradiation accurately identifies asymptomatic significant coronary artery disease. 2: To establish the...

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Lymphomas Hodgkin's disease |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON34730

**Source**
ToetsingOnline

**Brief title**
SCAR

### Condition

- Lymphomas Hodgkin's disease
- Coronary artery disorders

**Synonym**
radiation induced coronary artery disease

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** coronary disease, hogdkin's lymphoma, late treatment sequelae, radiotherapy

## Outcome measures

### Primary outcome

see objectives

### Secondary outcome

see objectives

# Study description

### Background summary

Survivors of Hodgkin*s lymphoma (HL) are known to have an increased risk of developing late treatment sequelae such as cardiovascular events due to coronary artery disease. At present no active screening is performed in these patients, since it is not known whether screening and subsequent treatment by means of revascularization is effective in reducing the risk of cardiovascular events in asymptomatic individuals.
In this phase II trial the efficacy and therapeutic consequences of screening for coronary artery disease by multi-slice CT (MSCT) among asymptomatic HL survivors will be evaluated

### Study objective

Primary objectives:
1: To determine whether CT- coronary angiography by MSCT as a screening method of HL survivors treated with mediastinal irradiation accurately identifies asymptomatic significant coronary artery disease.
2: To establish the prevalence of coronary abnormalities in HL survivors treated with mediastinal irradiation.

Secondary objectives:
1: To determine the frequency and type of subsequent interventions
2: To determine the total costs of screening and subsequent intervention in this cohort.
3: To evaluate the acceptance of cardiac screening and to assess quality of life among HL survivors by means of validated questionnaires.

### Study design

Eligible patients from our present follow-up population of HL survivors will be invited by mail for a following visit in the so called late-effects screening pathway of the outpatient clinic of the LUMC Department of Radiotherapy.
In this visit the pilot study will be introduced, oral and written information will be given and an informed consent form will be handed out. Eligible patients will also be asked to participate in a study of quality of life and acceptance of screening by means of completing validated questionairres (EORTC-QLQ-C30, FAS and INFO 25) before and after the cardiac screening. Participation in the quality of life part of this study is not mandatory for participation in the cardiac screening part of this study.
After consent for the cardiac screening has been obtained, patients will be referred to the LUMC Department of Cardiology (Prof. Dr. M. Schalij) for the standard cardiac screening which is part of the late effects screening care pathway. This will take place in one visit and will consist of a specific patient history and physical examination, fractionated serum cholesterol and glucose testing, a resting ECG, and (stress) echocardiogram.
In a separate visit contrast enhanced CT- coronary angiography will be performed at the Department of Radiology, according to the current existing LUMC radiology protocols. If significant coronary disease, defined as >= 50% stenosis of diameter of the lumen of the large coronary arteries is found, revascularization of the narrowed lumen by means of percutaneous coronary intervention (PCI) is considered indicated in compliance with existing LUMC cardiology protocols, and this will be discussed with the patient in a subsequent visit to the Cardiology Outpatient Department.

Intervention:
CT coronary-angiography, to be performed as a screening method (to indicate further diagnostic treatment procedures).

### Study burden and risks

Burden: - at least three visits to the radiation onclogy and cardiology out patient clinic. If intervention is needed, more visits (depending ionthe nature of intervention) will follow.

Risks: minimal risks of contrast allergy

## Contacts

**Public**
Academisch Medisch Centrum

postbus 9600
2300 RC Leiden
NL
**Scientific**
Academisch Medisch Centrum

postbus 9600
2300 RC Leiden
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

-at least 10 year disease free survival after mediastinal irradiation for Hodgkin lymphoma
-current age 40 - 60 yr

## Exclusion criteria

- current angina pectoris
- current treatment for cardiovascular disease (except hypertension, hypercholesterolemia or cardiac murmurs)
-known or symptomatic heart failure
-known contrast allergy
- known renal function impairment
-presence of life threatening disease

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-01-2011 |
| Enrollment: | 50 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 24-11-2010 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# 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 | NL31278.058.10 |