

Long-term cardio- and neurovascular effects of radiotherapy and chemotherapy in patients with Hodgkin's lymphoma

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The main objectives are :Cross-sectional:1. To investigate the extent of atherosclerotic disease of the carotid artery defined as: (a) the intima-media thickness (IMT) (b) the elasticity (c) the degree of stenosis2. To define the degree of...

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

Summary

ID

NL-OMON31544

Source

ToetsingOnline

Brief title

geen

Condition

- Lymphomas Hodgkin's disease
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

Hodgkin's disease

Research involving

Human

Sponsors and support

Primary sponsor: Interne Geneeskunde

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiovascular disease, Complications, Hodgkin's Lymphoma, Intima media thickness, Radiotherapy

Outcome measures

Primary outcome

The main parameters are the difference in IMT, the elasticity, the degree of stenosis

between the irradiated group and the non-irradiated HL group and to the control population.

The other main parameter is the extent of coronary atherosclerosis on MRI in the two patients groups.

Secondary outcome

To investigate if inflammatory markers which are known to be increased in age-related atherosclerosis are also increased in RT-induced atherosclerosis.

The amounts of cerebrovascular events; i.e. TIA or CVA and of cardiovascular disease; i.e. angina pectoris, myocardial infarction, cardiomyopathy, cardiac failure, rhythm-, conduction abnormalities and valvular dysfunction will be studied. Also endocrine dysfunction will be assessed.

Study description

Background summary

To obtain insight in the pathogenesis and extent of cardio- and neuro-vascular disease in survivors of Hodgkin's lymphoma (HL) with respect to former treatment modalities: radiotherapy (RT) and chemotherapy (CT).

Study objective

The main objectives are :

Cross-sectional:

1. To investigate the extent of atherosclerotic disease of the carotid artery defined as:

(a) the intima-media thickness (IMT)

(b) the elasticity

(c) the degree of stenosis

2. To define the degree of atherosclerotic disease of the coronary system by MRI.

Prospective:

To estimate the progress of the above mentioned research points, we will repeat the measurement after 5 years of follow-up.

Study design

The study is a cross sectional cohort study. After 5 years a prospective study will be conducted to estimate the progress of the above mentioned research points.

Study burden and risks

Patients and controls participating in the study will be evaluated twice during a total of 6 hours. The first visit consists of a global physical, neurological examination and duplex scanning of the carotid artery. Also 5 tubes of blood will be taken for base-line blood values and inflammatory markers. This visit will last for a maximal 3 hours. During the second visit a MRI of the coronary system is performed.

All procedures are with low risks and have a minimum of discomfort.

Contacts

Public

Selecteer

Koekoekslaan 1
3430 EM Nieuwegein

Nederland
Scientific
Selecteer

Koekoekslaan 1
3430 EM Nieuwegein
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients who have been treated for Hodgkin's lymphoma in the past and who survived at least 2 years. Age > 18 years.

Exclusion criteria

Psychiatric disease or inability to give informed consent.

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2007
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO	
Date:	20-10-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	04-12-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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

CCMO

ID

NL12714.100.06