Epidemiology and biology of the metabolic syndrome in adult survivors of childhood cancer.

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To investigate the frequency and the biology of the metabolic syndrome in childhood cancer survivors in order to find risk factors for cerebro- and cardiovascular diseases and to design preventive intervention strategies in indicated risk groups

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON35166

Source
ToetsingOnline

Brief title
Metabolic syndrome in childhood cancer survivors.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Lipid metabolism disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
cardiovascular diseases

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: deels patiëntenzorg;en KiKa. Toegevoegd gedeelte Stichting KOCR

Intervention

Keyword: childhood cancer survivor, late effects, metabolic syndrome

Outcome measures

Primary outcome

- blood pressure

- body composition

- (abdominal) obesity

- glucose metabolism

- lipidspectrum

Secondary outcome

-polymorphisms

-other parameters associated with the metabolic syndrome:

*biomarkers for endothelial function

*pro-inflammatory markers

*pro-thrombotic factors

*biomarkers for adiposity

*urine-analysis

- results of fitness test

Study description

Background summary

As currently the majority of children with cancer survives, the absolute number

of adult survivors is increasing. Therefore, long-term toxicity issues become increasingly important. In the general population the metabolic syndrome has become one of the major public health challenges worldwide as it identifies individuals at risk of both type 2 diabetes and cerebro- and cardiovascular disease. It is conceivable that adults who survived childhood cancer may be at risk for developing metabolic syndrome due to treatment related factors.

Study objective

To investigate the frequency and the biology of the metabolic syndrome in childhood cancer survivors in order to find risk factors for cerebro- and cardiovascular diseases and to design preventive intervention strategies in indicated risk groups

Study design

This will be a prospective cohort study.

The determinants of the metabolic syndrome will be investigated in a group of 600 childhood cancer survivors who have been treated in the ErasmusMC-Sophia Children's Hospital.
As the prevalence of these determinants is also increasing in the normal population, it is very important to investigate these determinants also in a group of healthy controlpersons, to be able to compare the survivors with he normal population.

Study burden and risks

Participation in this research will require approximately one day, with a maximum of 1 day and a few hours on a second day.
The risk of the imaging studies and the vena punction is minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient:
- history of childhood cancer
- treated in ErasmusMC-Sophia
- at least 18 years old
- minimum of 5 years after cessation of therapy
Control:
- preferrably brother or sister of the patient, if not available;
- friend or neighbour of survivor of same sex and approximately same age, within a range of 5 years.

Exclusion criteria

Patient:
- when partly treated in other country
Controls:
- when they also have a history of childhood cancer

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2009
Enrollment:	1200
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-07-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-02-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26325.078.08