prospective longitudinal assessment of cardiovascular toxicity of childhood cancer treatment

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Primary objectives1. To investigate prospectively the prevalence of cardiovascular damage due to cancer treatment and it*s change over time.2. To investigate markers of early and late toxicity of cardiovascular damage due to cardiotoxic treatment....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational non invasive

Summary

ID

NL-OMON32995

Source
ToetsingOnline

Brief title
CLEP2

Condition

- Cardiac disorders, signs and symptoms NEC
- Vascular disorders NEC

Synonym
cardiac dysfunction, decreased heartfunction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting Kinder Oncologie Groningen

(SKOG)

Intervention

Keyword: cardiovascular toxicity, childhood cancer treatment, longterm toxicity, prospective study

Outcome measures

Primary outcome

1. Prevalence of subclinical cardiac damage (diagnosed by echocardiography as

either systolic, diastolic or combined

dysfunction)

2. Prevalence of cardiovascular risk factors (blood pressure, vascular wall

changes, body composition and

metabolic syndrome)

3. Changes in intima media thickness in carotid-/femoral arteries after

treatment with anthracyclines and/or

thoracal/neckradiation.

Secondary outcome

NA

Study description

Background summary

In the last 15 years it has become clear that long-term survivors of childhood cancer, especially those treated with radiotherapy on the mediastinum and/or anthracyclines have a significantly increased risk of developing cardiovascular

late effects. More insight into the underlying pathophysiological mechanisms, the relationship between cardiovascular risks factors and the development of cardiovascular damage is needed to design suitable intervention strategies.

Study objective

Primary objectives
1. To investigate prospectively the prevalence of cardiovascular damage due to cancer treatment and it*s change
over time.
2. To investigate markers of early and late toxicity of cardiovascular damage due to cardiotoxic treatment.

Secundary objectives
1. To study cardiovascular risk factors during cancer treatment (like cardiovascular damage, body composition and
genetic susceptibility).
2. To generate a database of childhood cancer survivors with the purpose of prospective cardiovascular late effects
studies over prolonged periods of time

Study design

This is a prospective longitudinal non-randomised cohort study in newly diagnosed children who will be treated for cancer at the Pediatric Oncology Center Groningen.

Additional inclusion criteria are: age between 0 and 18 years at start of treatment, being able to understand the Dutch study information (patient and/or parent), and willingness to give written informed consent.

Study burden and risks

The non-invasive tests will be performed during treatment and routine follow-up visits and are partial standard care. As far as known no adverse events are linked to the described study procedures. As soon as insight has been gained into the prevalence of treatment induced cardiovascular disease, its progression and the role of additional risk factors, tools can be developed for secondary prevention and eventually primary prevention. Efficacious prevention or alleviation of cardiovascular disease due to cancer treatment may reduce treatment-related morbidity and mortality in long-term childhood cancer survivors and thus benefit their quality of life.

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

newly diagnosed childhood cancer patients
age 0-18 years
written informed consent

Exclusion criteria

inadequate knowledge of the dutch language for reading the information and writing informed consent

Study design

Design

Study type:	Observational non 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):	22-01-2010
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	12-10-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-08-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL28905.042.09