Early detection of cardiac dysfunction in childhood cancer survivors; a DCOG LATER study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23641

Source
NTR

Brief title
SKION LATER CARD

Health condition

Cardiotoxicity in childhood cancer survivors; Cancer treatment related cardiac dysfunction and heart failure

Sponsors and support

Primary sponsor: Princess Maxima Center for pediatric oncology, Amsterdam UMC (AMC), Radboudumc, SKION
Source(s) of monetary or material Support: Hartstichting, KiKA & Odas

Intervention

Outcome measures

Primary outcome

With the current project we would like to answer the following research questions:

1. What is the prevalence and what are treatment related and lifestyle related risk factors for late (>10 year follow up) asymptomatic systolic or diastolic cardiac dysfunction identified by echocardiography in CCS compared with sibling controls?

2. What is the prevalence and what are treatment related risk factors for abnormal biomarkers in CCS compared with sibling controls?

3. What is the prevalence and what are treatment related risk factors for abnormal ECG measurements in CCS compared with sibling controls?

4. What are early diagnostic markers for cardiac dysfunction, defined by echocardiographic measurements, in blood and ECG by a cross sectional measurement in CCS and controls.

5. What are the gender differences in prevalence, risk factors for late abnormal echocardiographic measurements, late concurrent abnormal biomarkers and late concurrent ECG abnormalities

6. What are optimal recommendations for the cardiac follow-up of CCS

Secondary outcome

N/A

Study description

Background summary

The survival of children with cancer has improved considerably over the last decades. Nevertheless, there is a great concern about the long-term side effects of their treatment. Our previous study showed that the estimated risk of symptomatic cardiac disease is 9.6%, 40 years after treatment. Known treatment related risk factors for symptomatic cardiac events are anthracyclines, mitoxantrone and radiotherapy to the heart region. In the current Dutch guidelines, all survivors with these risk factors are screened by echocardiography every 3- 5 years for cardiac abnormalities, and are treated with heart failure medication when ejection fraction is <40% and/or if symptoms occur. To identify survivors at risk who might benefit from early treatment more evidence based knowledge is mandatory. In this line, we hypothesize that assessment of more sensitive echo- and electrocardiographic measurements, and/ or biomarkers will allow earlier recognition of asymptomatic patients with cardiovascular disease who are at higher risk of developing cardiac events, and provide also data on low risk groups.

This study will be part of the multidisciplinary Dutch Childhood Oncology Group (DCOG) research program for patient care and research into long-term effects after childhood cancer

(LATER). We have identified a DCOG- LATER cohort of 6168 Dutch childhood cancer survivors (CCS) treated between 1963 and 2001. In the DCOG-LATER program all alive CCS will be invited for several sub-studies and diagnostic tests performed at the DCOG-LATER outpatient clinic. Our aims for the present cross-sectional cardiac DCOG-LATER study are 1) to estimate the magnitude of risk and risk factors for subclinical cardiovascular disease in CCS and 2) to estimate the diagnostic value of echo- and electrocardiographic parameters and biomarkers in detecting cardiac disease by performing these tests in a very large cohort. Furthermore, we will collect information on gender related morbidity, overall comorbidities and important confounders. The results of the study will enable us to develop more informed long-term follow-up screening guidelines and ultimately an intervention strategy aimed to deliver timely therapy to reduce cardiac events, either during the childhood cancer treatment or in the follow-up period.

Study design

N/A

Intervention

N/A

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Eligible survivors are 5-year childhood cancer survivors (CCS) diagnosed before the age of 18 years, between 1/1/1963 and 12/31/2001 with a malignancy according to the third edition of the International Classification of Childhood Cancer. We only included CCS who were living in the Netherlands at the time of childhood cancer diagnosis and who were treated in one of the Dutch pediatric oncology/hematology centers (Academic Medical Center Amsterdam, VU University Medical Center, Leiden University Medical Center, Erasmus Medical Center, University Medical Center Groningen, Radboudumc, and University Medical Center Utrecht). This study will include 4 risk groups; risk group 1: CCS who have received anthracyclines, mitoxantrone, or irradiation to the heart region; risk group 2 (max n=100):

cyclophosphamide only (no anthracyclines, mitoxantrone, or irradiation to the heart region, ifosfamide or vincristine); risk group 3 (max n=100): ifosfamide only (no anthracyclines, mitoxantrone, or irradiation to the heart region, cyclophosphamide or vincristine); risk group 4 (max n=100): vincristine only (no anthracyclines, mitoxantrone, or irradiation to the heart region, ifosfamide or cyclophosphamide), irrespective current age. For the comparison group 500 healthy siblings will be included.

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2017
Enrollment:	2200
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-07-2018
Application type:	First submission

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
NTR-new	NL7259
NTR-old	NTR7481
Other	: CVON2015-21

Study results