Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; DCOG LATER Q2008 onderzoek:
Bone mineral density and body composition in survivors of childhood cancer

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• To evaluate the proportion of childhood cancer survivors that reach peak bone mass• To evaluate the incidence rate of fractures of CCS as compared to normal controls• To investigate patients at (treatment or diagnosis related) risk for decline of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47723

Source
ToetsingOnline

Brief title
DCOG LATER Q2008 - bone

Condition

- Other condition

Synonym
impaired fitness and motor impairment, osteonecrosis, osteoposoris

Health condition

botten, bewegingsapparaat en fitheid

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland
Source(s) of monetary or material Support: Quality of life gala

Intervention

Keyword: fitness, osteogenic late effects, pediatric oncology, survivor

Outcome measures

Primary outcome

1- Prevalence and exogenous and genetic risk factors of osteopenia and osteoporosis and subsequent fractures, per persons years in CCS. 2- Prevalence of over- and underweight as expressed by BMI and LBM. 3- Treatment and diagnosis related risk factors for irreversible osteonecrosis. 4- Treatment and diagnosis related risk factors for impaired motor function and muscle strength

Secondary outcome

N.A.

Study description

Background summary

Advances in diagnosis and treatment of childhood cancer over the last decades have dramatically increased long-term survival. As a result, the numbers of childhood cancer survivors (CCS) are growing and it has become increasingly clear that the former disease and its treatment can significantly impair long-term health. The need for long-term follow-up is uniformly recognized.

Research focusing on identification and characterization of high-risk populations is an essential foundation on which to build evidence-based recommendations for long-term follow-up. Furthermore, research focusing on more accurate screening tests and effective interventions is needed to reduce excess morbidity and mortality in CCS. This DCOG LATER Q2008 - study phocuses on late toxicity involving bone, bodycomposition (underweight and overweight), motor performance and muscle mass and strength, which are indicators of frailty

Study objective

• To evaluate the proportion of childhood cancer survivors that reach peak bone mass
• To evaluate the incidence rate of fractures of CCS as compared to normal controls
• To investigate patients at (treatment or diagnosis related) risk for decline of BM(A)D at an earlier age as compared to the normal population. (baseline for future longitudinal studies)
• To identify childhood cancer survivors at risk for osteoporosis based on evaluation of genetic variation
• To evaluate the prevalence of osteopenia in a full cohort of childhood cancer survivors in relation to Calcium intake and physical activity
• To study the correlation between age of menopause and bone mineral density
• To identify childhood cancer survivors at risk for osteoporosis based on evaluation of folate metabolism
• The body composition as measured by DXA with in a full cohort of childhood cancer survivors in order to be able to evaluate type of cancer, therapy and exogenic factors as risk factors for an altered body composition after surviving childhood cancer.
• To study the long term outcome of patients with osteonecrosis during therapy
• To investigate the risk of and risk factors of irreversible osteonecrosis as a long term side effect of treatment childhood cancer
• To investigate the motor performance and fitness status of long term survivors of childhood cancer
• To investigate denominators of impaired motor performance and fitness after childhood cancer (disease, chemo, surgery)
• To investigate the impact of osteonecrosis and fracture rate on motor ability status in long term survivors of childhood cancer
• To evaluate impaired muscle mass and muscle strenght in long term survivors of childhood cancer
• To evaluate the prevalence of (pre)frailty in long term survivors of childhood cancer

Study design

The study with cross sectional design will consist of an anamnesis and physical examination, a DXA scan, a questionnaire, a 6 minute walking test, strength and

mobility tests and a venapuncture. For a substantial part of the study population, these tests will be part of regular patient follow up as defined by the guidelines for screening for late toxicity in CCS. Data will be collected anonymously in a central database.

Study burden and risks

The largest part of the participants (n=2500 will get an outpatient visit, DXA scan and venapuncture as part of their regular follow up based on screening guidelines for CCS. For this group only the questionnaire (10 minutes), and the 6 minute walking test. For the patients for which DXA scan is not included in the guideline extra time (30 minutes) and radiation exposition has to be considered (dose equivalent of ± 10µSv). This dose is equivalent to 1 or 2 days natural radiation exposition in the open air in the Netherlands.

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

All patients who were treated for childhood cancer (before age 18) in one of the Pediatric Oncology Centers between 1960 and 2001 and who survived for at least 5 years after diagnosis will be included in the DCOG LATER study. Participating centres are located in Amsterdam (VU University Medical Center (VUMC)), Groningen (Children's Cancer Center/ University Medical Center Groningen (UMCG)), Rotterdam (Rotterdam Erasmus MC-Sophia (REMC-S), Nijmegen (University Medical Center Nijmegen (UMCN)), Leiden (Leiden University Medical Center (LUMC) and Utrecht (Princess Máxima Center for Pediatric Oncology (PMC)). From this cohort, 2500 childhood cancer survivors will be asked to participate in this study. (BMI will be assessed in all 7000 survivors as regular patient care).

Exclusion criteria

diagnosis of childhood cancer with survival less than 5 years, age at diagnosis >17 years or diagnosis while residing in foreign country, no cardiologic impairment(fitness)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2016
Enrollment:	2500
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35000.018.11