Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; DCOG-LATER Q2008 study;
Long-term renal effects in Dutch survivors of childhood cancer

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON47761

Source
ToetsingOnline

Brief title
DCOG- LATER Q2008 - renal

Condition

- Renal disorders (excl nephropathies)

Synonym
late nefrotoxic effects of treatment for childhood cancer, renal damage in long-term survivors of childhood cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: late effects, pediatric oncology, renal, survivor

Outcome measures

Primary outcome

1) Prevalence of glomerular dysfunction in 5-year survivors of childhood cancer

treated with possible nefrotoxic modalities (comparisons: high

risk versus low-risk group; high-risk group versus reference values from

general population; low riskgroup versus reference values general

population)

2) Prevalence of tubular dysfunction in 5 year CCS treated with potential

nefrotoxic therapy (comparisons: high

risk versus low-risk group; high-risk group versus reference values from

general population; low riskgroup versus reference values general

population)

3) Treatment related-risk factors for abnormal diagnostic renal fucntion tests

4) Hypertension (in relation to glomerular function)

5) Diagnostic value of Cystatin C voor glomerular dysfunctie

Secondary outcome

not applicable

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.

The SKION LATER Q2008 - renal study phocuses on late renal toxicity in CCS in relation to (potentially) nefrotoxic modalities with varying doses and administered at different ages.

Study objective

Aim of the study is to assess
1) the prevalence of glomerular dysfunction and tubular dysfunction in childhood cancer survivors treated with possible nefrotoxic therapy.
2) the treatment related risk factors for glomerular and/or tubular dysfunction in childhood cancer survivors treated with possible nefrotoxic therapy
3) the diagnostic value of cystatin C in detecting glomerular dysfunction in childhood cancer survivors?
4) the relationship between glomerular function and hypertension
5) the relationship between renal factors and bone density (together with the SKION-LATER Q2008-bone projectgroup)
6) the relationship between renal dysfunction and growth (together with the SKION-LATER Q2008-endocrinology projectgroup)
7) the relationship between renal dysfunction and cardiovasculair risk (together with the SKION-LATER Q2008-cardiology)

Study design

This cross-sectional study consists of an anamnesis, a physical examination (weight, height, bloodpressure), a venapuncture and the provision of a urine sample. All examinations are performed as part of regular patient follow-up care as defined by the guidelines for screening for late renal toxicity in CCS. In order to perform some additional blood and urine analyses for study purposes some extra blood and urine will be collected for the patient. However, no extra

venapuncture will have to be performed. All study parts will be performed on the same day during a visit to the Late Effects Outpatient Clinic for patient follow-up care. For a sugroup of 100 survivors of the VUmc and AMC-cohort an ambulant 24 hours bloodpressure measurement will take place.Collected data will be stored anonymously in a national database and will eventually be related to previous treatment data.

Study burden and risks

Patients will be invited to visit the Late Effects Outpatient Clinic for their regular follow-up care according to the nationwide screening guidelines. During this visit to the outpatient clinic they will undergo a physical examination (weight, height, bloodpressure), a venapuncture and they will be asked to provide a urine sample as part of their follow-up care. For study reasons some additional blood will be drawn (8ml in 1000 patients and 2 ml in 2000 patients) during the same venapuncture as that required for patient care. Therefore there is no additional study risk and burden for the patient.

It is possible that the study will lead to new insights regarding the patients health. If renal damage is established it is of benefit to the patient to know about this so appropriate treatment can be initiated in order to improve prognosis and reduce the number of complications in the long run.
In addition, the study will provide an increased insight into the risks and extent of renal damage and its complications following childhood cancer in general and after several treatment modalities in particular. This information may be of great value to future patients having to undergo treatment for childhood cancer which includes a (possible) nefrotoxic modality. For instance, treatment protocols may, where possible, be adjusted in order to decrease toxicity without reducing survival, better screeningmethods may become available, and interventions may be applied sooner.

In order to fully evaluate the prevalence, extent, and progression of renal damage following treatment of childhood cancer it is important to also look at the relatively short term (5-10 jaar after diagnosis) damage and complications. Prevalence and extent of damage found 5-10 years after diagnosis can then be compared to the prevalence and extent of damage in a group of survivors who are more than 10 years after diagnosis. The group of patients 5-10 years after diagnosis in this study also includes minors, although this group is relatively small (135 out of 3000). These minors will also be seen at the late effects outpatients clinic for regular follow-up care which also includes a physical examination, venapuncture and urine collection. Therefore, there is no additional study risk or burden for minors either since blood for the study will be collected during the same venapuncture required for follow-up care.

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 seven Pediatric Oncology Centers between 1960 and 2004 and who survived for at least 5 years after diagnosis will be included in the SKION 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, 2000 childhood cancer survivors who previously received potentially nefrotoxic treatment will be asked to participate in the DCOG-LATER

Q2008 nefrology study.

Exclusion criteria

diagnosis of childhood cancer with survival less than 5 years, age at diagnosis >18 years or diagnosed while residing in foreign country, no nefrotoxic treatment

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:	Recruitment stopped
Start date (anticipated):	04-05-2016
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2016

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:	28-11-2017
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	NL35046.018.11