

Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 - Metabolic syndrome parameters in adult survivors of childhood cancer

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• To study denominators of the metabolic syndrome in all survivors of childhood cancer • To compare the occurrence with previous disease and treatment components to identify subgroups at risk Metabolic syndrome • To study the overall frequency of the...

Ethical review

Approved WMO

Status

Recruitment stopped

Health condition type

Glucose metabolism disorders (incl diabetes mellitus)

Study type

Observational invasive

Summary

ID

NL-OMON47840

Source

ToetsingOnline

Brief title

SKION LATER Q2008 - metabolic syndrome

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Metabolism disorders NEC

Synonym

adiposity, high bloodpressure

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland

Source(s) of monetary or material Support: Quality of life gala

Intervention

Keyword: diagnostic tests, late effects, metabolic syndrome, pediatric oncology

Outcome measures

Primary outcome

Prevalence of metabolic syndrome or its denominators (body composition, hypertension, DM, Fat spectrum)

Secondary outcome

nvt

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 - metabolic study focuses on the prevalence of the metabolic syndrome in CCS. Since the metabolic syndrome predisposes patients for cardiovascular disease, for which CCS are at risk for other reasons as well, this subject seems very relevant in this patient group.

Study objective

- To study denominators of the metabolic syndrome in all survivors of childhood cancer
- To compare the occurrence with previous disease and treatment components to identify subgroups at risk Metabolic syndrome
- To study the overall frequency of the metabolic syndrome in a full cohort of childhood cancer survivors
- To study the denominators of the metabolic syndrome in all survivors of childhood cancer separately in order to be able to identify risk groups for these endpoints after surviving childhood cancer: (body composition, hypertension, DM, Fat spectrum)
- To study the correlation of these denominators of metabolic syndrome with previous disease and treatment components to identify risk factors
- To correlate the value of of biomarkers (leptine, ,adiponectiine etc) and proinflammatory markers (TNF, alpha, Il6) with the risk of metabolic syndrome

Study design

The study involves a cross-sectional study of a retrospective nationwide cohort of 5-year survivors of childhood cancer (diagnosed 1960-2003) in the Netherlands. besides, 500 sibling controls of survivors will be approached. We estimate that the total cohort will include 7000 survivors and controls

Study burden and risks

The survivors will be invited for the Q2008 SKION LATER study close to a visit to the LATER out patient clinic. this visit will be combined with the out patient visit for regular patient care. extra blood will be drawn during a venapuncture for regular patient care. the only real burden of the study is that the CCS will can not eat 8 hours in advance of the venapuncture.

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 2004 and who survived for at least 5 years after diagnosis will be included in the SKION LATER- metabolic syndrome 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)).

Exclusion criteria

diagnosis of childhood cancer with survival less than 5 years, age at diagnosis >17 years or diagnosis while residing in foreign country

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: 5000
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: 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	NL32117.018.10