Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 onderzoek - Reproductive potential in male survivors of childhood cancer

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1. To assess the prevalence of severe male subfertility in adult male survivors of childhood cancer in relation to type and intensity of treatment and age at time of treatment. 2. To assess the diagnostic value of inhibin B and AMH for the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON47702

Source
ToetsingOnline

Brief title
SKION LATER Q2008 - male fertility

Condition

- Endocrine disorders of gonadal function
- Sexual function and fertility disorders

Synonym
late effects, long-term effects

Research involving
Human

Sponsors and support

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

Intervention

Keyword: fertility, late effects, male, pediatric oncology

Outcome measures

Primary outcome

prevalence of subfertility diagnostic value of inhibin B and AMH reproductive

history and health of offspring

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. this research proposal on fertility in male childhood cancer survivors is part of the large national study and focuses on the effect of previous anti cancer treatment on fertility when the patient has reached adulthood.

Study objective

1. To assess the prevalence of severe male subfertility in adult male survivors of childhood cancer in relation to type and intensity of treatment and age at time of treatment. 2. To assess the diagnostic value of inhibin B and AMH for the prediction of male subfertility in adult survivors of childhood cancer. 3. To assess the reproductive history (method of conception, number of life births, pregnancy outcomes) in adult survivors of childhood cancer in relation to type and intensity of treatment and age at time of treatment. 4. To assess the health of offspring from male childhood cancer survivors

Study design

The study involves a cross-sectional study of a retrospective nationwide cohort of 5-year survivors of childhood cancer (diagnosed 1960-2001) in the Netherlands. 2700 survivors will be included.

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. the visit for the research questions will be linked to visits to the clinic for regular patient care. for the study, extra blood (15 minutes) will be drawn when a venapuncture is done for patient care. extra questionaire has to be filled in (5-15 minutes) and semenanalysis will be done (10 - 20 minutes). participation will not benefit the survivors, except when they wish to have information on their fertility. it is known from earlier research that a large proportion of the survivors has such a wish. the group of survivors benefits from the study since they can be informed on risks of infertility and better tools will be available to measure infertility. future pediatric cancer patients benefits since with the results of the study new treatment protocols can be designed with less toxicity.

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

adult (> 18 yrs of age) male 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 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)).

Exclusion criteria

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

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:	2700
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-01-2016
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	NL34909.018.10