# 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

Published: 08-05-2015 Last updated: 04-05-2024

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

**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**

#### **Public**

Stichting Kinderoncologie Nederland

Heidelberglaan 25 Utrecht 3584CS NI

# Scientific

Stichting Kinderoncologie Nederland

Heidelberglaan 25 Utrecht 3584CS NL

# **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

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## 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