Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project (DCOG LATER study)
DCOG LATER substudy: Sexual function and psychosexual development in long-term childhood cancer survivors

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This DCOG-LATER project proposal aims to characterize the overall, disease and treatment-related risks of sexual dysfunction and delays in psychosexual development in a Dutch cohort of 5-year CCS treated in the period 1960-2001 and to evaluate the...

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

Summary

ID

NL-OMON47606

Source
ToetsingOnline

Brief title
DCOG LATER - sexual function and psychosexual development

Condition

- Other condition
- Sexual function and fertility disorders
- Lifestyle issues

Synonym
sexual function and psychosexual development

Health condition

psychosexuele ontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Kinderoncologie Nederland
Source(s) of monetary or material Support: Stichting Quality of Life gala;KiKa;KWF/Alpe d'Huzes

Intervention

Keyword: late effects, pediatric oncology, sexual function and psychosexual development, survivor

Outcome measures

Primary outcome

1. Prevalence of sexual dysfunctions

2. Disease and treatment related risk factors for sexual dysfunctions

3. Prevalence of distress associated with sexual dysfunction

4. Relationship factors

5. Prevalence of delayed psychosexual development

6. Disease and treatment related risk factors for delayed psychosexual

development

7. Free Androgen Index (FAI, based on serum testosteron and sex hormone binding

globulin levels))

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 number of childhood cancer survivors (CCS) is growing and it has become increasingly clear that the former disease and its treatment can significantly impair long-term health and Health-Related Quality Of Life (HRQoL). More insight into the consequences of childhood cancer and its treatment is needed to develop optimal care for survivors of childhood cancer and provide interventions that will improve life after cancer.
Cancer and its treatment, as well as several late effects of treatment, may damage one or more of the physiological systems needed for a healthy sexual response and affect developing sexual behaviors, attitudes and identity. It may put the patient at risk for delays in achieving psychosexual milestones and an impaired gender identity, factors which in turn may also influence sexual behaviour and function later in life. Only two studies have assessed sexual function in CCS. However, the impact of previous cancer treatment on different biological as well as psychosocial factors involved in sexual behaviour have not been studied in detail.
This project is part of the multidisciplinary Dutch Childhood Oncology Group (DCOG) program for patient care and research into long-term effects after childhood cancer (LATER) and currently involves over 20 specific PhD projects focusing on various late effects.

Study objective

This DCOG-LATER project proposal aims to characterize the overall, disease and treatment-related risks of sexual dysfunction and delays in psychosexual development in a Dutch cohort of 5-year CCS treated in the period 1960-2001 and to evaluate the extent to which sexual dysfunction is associated with distress. In addition, the extent to which sexual dysfunctions may be associated with other major biological, psychological and sociocultural risk factors for sexual dysfunction will be examined.
Specific aims include, to study in male and female 5-year survivors of childhood cancer in the Netherlands:
1) the prevalence of sexual dysfunctions (compared to controls)
2) disease and treatment related risk factors for sexual dysfunction (biological risk factors)
3) the extent to which sexual dysfunctions are associated with distress (psychological factors)
4) the effects of relationship factors on sexual dysfunctions (socio-cultural factors)
5) the effects of other major biological, psychological and sociocultural

risk factors on sexual dysfunctions (age at diagnosis, age at study, medication use, co-morbidities, depression, religion, life style factors)
6) the prevalence of delays in psychosexual development (compared to controls)
7) disease and treatment related risk factors for delays in psychosexual development and their association with sexual dysfunctions
8) the correlation between sexual dysfunctions and the Free Androgen Index (FAI)

Study design

The general study design involves a nation-wide multicentre retrospective cohort study. All CCS in the Netherlands are offered regular follow-up screening according to national, uniform, evidence-based guidelines in one of the seven Dutch long-term follow-up clinics, and for this substudy on sexual function and psychosexual development all eligible CCS (n=5166 adults) will be invited to participate in the proposed study. In addition 1500 controls, both siblings and controls from the general population, will be invited to participate. Comparison with siblings allows to control for genetic background, the microsocial status and attitude towards sex. Comparing CCS with controls from the general population will reveal differences on a macrosocial environmental level.
For the specific project described in the current proposal survivors will be asked to complete questionnaires on sexual function, sexual distress and psychosexual development including their satisfaction with past and current relationships. In addition, serum levels of total testosterone and sex-hormone binding globuline (SHBG) will be in order to distinguish endocrine causes of sexual dysfuntion from psychosocial causes.

Study burden and risks

For all participants (patients and controls) the study consists of completing 3 questionnaires (sexual function, sexual distress, psychosexual development including relationship factors) and providing a blood sample (they can also choose to not provide a blood sample and only compltete the questionnaire. Completing the questionnaire will take approximately 35-45 minutes. Bloodsampling in patients will primarily be performed at the same time that blood is drawn for patient care so that no extra venapuncture is required. For patients not requiring blood sampling for patientcare or not willing to participate in patient care, and controls, venapunction will be performed for research purposes only. However, both questionnaires and blood sampling carry along little to no risk. The total study time including questionnaires and venapunction will be 50 minutes maximum.

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

The general study design involves a nation-wide multicentre retrospective cohort study including the entire DCOG-LATER cohort of CCS according to the DCOG-LATER inclusion criteria:
1) Patients treated for childhood cancer in one of the 7 pediatric oncology centres between 1960-2001.
2) A histological verified diagnosis of malignancy covered by the ICCC3 and including long-term survivors of severe forms of Langerhans Cell Histiocytosis treated with chemotherapy and/or radiotherapy.
3) Age 0-17 years at diagnosis malignancy.
4) Survival at least 5 years from diagnosis.
Additional inclusion criteria apply for the DCOG-LATER sexual function and psychosexual development study:

1) Alive at time of study
2) Age 18 years or older
3) No severe mental retardation
4) Sufficient understanding of the Dutch language to complete the questionnaires.

Exclusion criteria

1) Treated for childhood cancer after 2001
2) less than 5 year survival from diagnosis
3) age at time of study less than 18 years
4) living abroad at time of study
5) mental retardation
6) insufficient knowledge of dutch language to complete questionnaires

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:	6500
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2015
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:	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	NL35001.018.12