Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 onderzoek: Hyposalivation in long-term survivors of pediatric cancers following different treatment regiments.

Published: 08-05-2015
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* To estimate the prevalence of hyposalivation and xerostomia in pediatric cancer survivors treated with different cancer regimens (e.g., H&N RT, TBI, CT, or those who developed cGVHD following allogeneic stem cell transplantation).* To describe...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Salivary gland conditions
Study type	Observational invasive

Summary

ID

NL-OMON47501

Source
ToetsingOnline

Brief title
SKION LATER Q2008 - SALI

Condition

- Salivary gland conditions

Synonym
dry mouth, xerostomia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hyposalivation, oral symptoms, xerostomia

Outcome measures

Primary outcome

- reduced unstimulated and stimulated salivary flow and Patient Reported

Outcomes indicative for xerostomia

- association between salivary flow measurements and complaints indicative for

xerostomia

- patient and therapy related risk factors for hyposalivation and xerostomia

- association between xerostomia and oral-health-related quality of life

- selected microorganisms and markers related to disease, oral function and

defense mechanisms in oral fluid samples.

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 - hyposalivation study phocuses on oral toxicity in CCS

Study objective

* To estimate the prevalence of hyposalivation and xerostomia in pediatric cancer survivors treated with different cancer regimens (e.g., H&N RT, TBI, CT, or those who developed cGVHD following allogeneic stem cell transplantation).
* To describe if any concordance is present between objective salivary flow measurements and patient-reported outcomes indicative for xerostomia.
* To assess putative patient-related and therapy-related risk factors.
* To examine the association between xerostomia and oral-health-related quality of life.
* To assess selected microbiological parameters and (glyco)proteins in whole salivary samples that are associated with oral infection, defense mechanisms or thirst sensation.

Study design

This study involves measurement of unstimulated and stimulated salivary flow and taking of a whole saliva sample. Also, an oral health questionnaire will be completed by the study participants.
(This study is part of a larger late effects study as described)

Study burden and risks

The burden is limited since investigation of salivary production is not painful and invasiveness is limited. No risks associated.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
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 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)). From this cohort, 300 childhood cancer survivors (100 who received irradiation to head or neck, 100 with a history of chronic graft versus host disease and 100 treated with chemotherapy but not with radiotherapy) will be asked to participate in the salivary study

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:	300
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2015
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:	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	NL35042.018.11