

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Salivary gland conditions
<b>Study type</b>	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 focuses 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**

### **Public**

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Heidelberglaan 25  
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### **Scientific**

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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