# SKION LATER Q2008 onderzoek: Fatigue in childhood cancer survivors

Published: 12-04-2013
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1. To assess the test characteristics (specificity, sensitivity, positive predictive value and negative predictive value) and cut-off value for severe fatigue of the VVV as screenings test for fatigue compared to the CIS 20 R . 2. To evaluate the...

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

## Summary

### ID

NL-OMON47846

**Source**
ToetsingOnline

**Brief title**
SKION LATER Q2008 fatigue

### Condition

- Other condition

**Synonym**
fatigue as late effect of treatment for childhood cancer

**Health condition**

vermoeidheid na kanker

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** fatigue, late effects, pediatric oncology, questionnaires

## Outcome measures

### Primary outcome

The individual diagnostic value of the VVV in detecting cancer related fatigue

Prevalence of concentration problems (CIS 20 R >= 19) in survivor group and

control group The influence of cancer and cancer treatment on fatigue in

childhood cancer survivors. The influence of depression and reduced quality of

life on fatigue in childhood cancer survivors. The influence of organ

dysfunction on fatigue in childhood cancer survivors.

### 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 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 - fatigue study phocuses

on fatigue problems in CCS.

### Study objective

1. To assess the test characteristics (specificity, sensitivity, positive predictive value and negative predictive value) and cut-off value for severe fatigue of the VVV as screenings test for fatigue compared to the CIS 20 R . 2. To evaluate the prevalence of cancer(treatment) induced concentration problems in the survivors group compared to healthy controls. 3. To estimate the prevalence of fatigue in childhood cancer survivors in relation to diagnosis, treatment and age of treatment. 4. To estimate the prevalence of fatigue in childhood cancer survivors in relation to mental health and quality of life scores. 5. To estimate the prevalence of fatigue in childhood cancer survivors in relation to neurocognitive outcomes. 6. To estimate the prevalence of fatigue in childhood cancer survivors in relation to organ dysfunction and body composition.

### Study design

All survivors of childhood cancer will be invited for a visit at the LATER out patient clinic. For this study SKION LATER Q2008 - Fatigue, questionnaires will be filled in by the survivors of childhood cancer and their siblings who are 12 years or older ( VVV and CIS 20 test).

### Study burden and risks

The survivors will be invited for the Q2008 SKION LATER-fatigue study close to a visit to the LATER out patient clinic. The completion of questionnaires will not take more than 15 minutes.

## Contacts

**Public**
Stichting Kinderoncologie Nederland

Heidelberglaan 25
Utrecht 3584CS
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**Scientific**
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Heidelberglaan 25
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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)).

## 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

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| Study type: | Observational non invasive |
| Intervention model: | Other |

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| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Basic science |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-05-2016 |
| Enrollment: | 11800 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 12-04-2013 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 02-02-2015 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 05-02-2015 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 05-01-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 06-10-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |

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| 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 | NL34983.018.10 |