Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 research:
Is pulmonary dysfunction a late effect of cyclophosphamide treatment?

Published: 23-01-2015
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to assess the pulmonary toxicity in patients treated with cyclophosphamide compared to a control group

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON47559

Source
ToetsingOnline

Brief title
SKION LATER Q2008 - pulmonology

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
pulmonary dysfunction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: late effects, lung function, pulmotoxicity

Outcome measures

Primary outcome

Abnormal PFT, defined as TLC/FVC <75% (restrictive dysfunction) of predicted

for age and sex matched controls of a normal population.

Other PFT parameters, i.e. FEV1%FVC <75% (obstruction) and/or DLCO/TLCO <75%

(diffusion).

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 - pulmonology study phocuses on late pulmonary toxicity in CCS

Study objective

to assess the pulmonary toxicity in patients treated with cyclophosphamide

compared to a control group

Study design

In 2 groups of childhood cancer survivors (CCS, each 260 patients) pulmonary late effects will be assessed by a pulmonary function test:
- CCS treated with cyclophosphamide but no other potentially pulmotoxic treatment modalities (chemo and/or radiotherapy)
- CCS treated with neither cyclophosphamide nor any other potentially pulmotoxic treatment modalities (chemo and/or radiotherapy)

Study burden and risks

no risks associated with the pulmonary function test. The test is not painful, patients wil have to blow in a tube

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

childhood cancer survivors (CCS) who either received cyclophosphamide (Cy) treatment but no other potentially pulmotoxic treatment or who received neither Cy nor any other potentially pulmotoxic treatment

Exclusion criteria

childhood cancer survivors who received potentially pulmotoxic treatment

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:	520
Type:	Actual

Ethics review

Approved WMO

Date:	23-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-01-2016
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	NL35002.018.11