Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 onderzoek:
Impaired splenic function in long-term survivors of childhood cancer; diagnostic and therapeutic strategies.

Published: 09-12-2016
Last updated: 27-04-2024

Primary aims:1. To assess the efficacy of pneumococcal vaccination in patients with impaired splenic function after cancer therapy. 2. To compare the number of IgM memory B-cells of survivors after splenectomy with survivors who received TBI, and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spleen, lymphatic and reticuloendothelial system disorders
Study type	Observational invasive

Summary

ID

NL-OMON47549

Source
ToetsingOnline

Brief title
DCOG LATER Q2008 - spleen

Condition

- Spleen, lymphatic and reticuloendothelial system disorders

Synonym
impaired splenic function in long-term survivors of childhood cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: late effects, pediatric oncology, spleen, survivor

Outcome measures

Primary outcome

• Individual diagnostic value of IgM memory B cells after irradiation over the

spleen.

• The number of hypo- or asplenic patients with vaccine failure.

Secondary outcome

• Duration of protection after pneumococcal vaccination.

• The number of survivors with hyposplenism after irradiation over the spleen

related to the dose of irradiation and time interval from irradiation assessed

by the number of IgM memory B-cells. .

Study description

Background summary

The SKION LATER Q2008 spleen study focuses on the decreased functioning of the spleen in long term survivors of childhood cancer. Patients with functional or anatomic asplenia are at significantly increased risk of overwhelming infection, particularly involving the encapsulated bacteria Streptococcus pneumoniae and Haemophilus influenzae. According to the current guidelines, patients should receive pneumococcal vaccination to prevent infection. However, in patients with lymphoproliferative disorders, the antibody level declines more rapidly and insufficient vaccinal response has been reported in

splenectomized patients with hematological diseases. Therefore, it is important to study the functioning of the spleen in the population of survivors of childhood cancer who have received total body irradiation, irradiation of the spleen or those who have undergone splenectomy. Next to that, the level and extent of the antibody response needs to be studied in patients who have been vaccinated.

Study objective

Primary aims:
1. To assess the efficacy of pneumococcal vaccination in patients with impaired splenic function after cancer therapy.
2. To compare the number of IgM memory B-cells of survivors after splenectomy with survivors who received TBI, and survivors irradiated over the spleen, in order to investigate the value of IgM memory B-cells in the assessment of splenic function.
Secondary aims:
1. To examine the vaccination status of long-term survivors with impaired splenic function.
2. To analyze, in a cross-sectional study, the duration of antibody response after pneumococcal vaccination in long term survivors.
3. To examine the relation between IgM memory B cells and antibody response after pneumococcal vaccination in survivors with impaired splenic function after cancer therapy.

Study design

Medical assessment and additional diagnostic tests:
- Medical history: Date of splenectomy/ date, dose and field of irradiation. Vaccinations and date of vaccinations, antibiotic prophylaxis, severe documented infections.
- Blood analysis T=0: Survivors (n=100): Flow cytometry-based immunophenotyping
- Blood analysis T=0: Survivors (n=469) Pneumococcal antibodies MOPA recently modified into a multiplex opsonophagocytosis killing assay

Long term survivors with hypo-or asplenia:
Prophylactic vaccination according to the RIVM guidelines for the survivors who were not vaccinated according to the guidelines (patient care; max 469 survivors): T=1: Three weeks after the last vaccination: Pneumococcal antibodies.

Study burden and risks

Vaccination of childhood cancer survivors will be performed according to the Dutch clinical guidelines for patients with impaired splenic function (regular

patient care). Burden for patients is an extra visit to the local hospital for a venapuncture to obtain 4 ml blood, 3 weeks after the Pneumovax vaccination. Besides 10 ml extra blood will be taken for research questions when patients get venapunctures for regular patient care.

Contacts

Public
Stichting Kinderoncologie Nederland

Heidelberglaan 25
Utrecht 3584CS
NL
Scientific
Stichting Kinderoncologie Nederland

Heidelberglaan 25
Utrecht 3584CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
Inclusion of all survivors aged >=18 years, after 1) splenectomy, 2) irradiation over the spleen and 3) total body irradiation

Exclusion criteria

diagnosis of childhood cancer with survival less than 5 years, age at diagnosis >17 years or diagnosis while residing in foreign country, survivors who are not capable of giving informed consent

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):	25-10-2017
Enrollment:	469
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2016
Application type:	First submission
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	NL35041.018.11