Medical assessment of adverse health outcomes in Dutch childhood cancer survivors; a nationwide project; SKION LATER Q2008 onderzoek: Thyroid function, in children and adults, after treatment for childhood cancer

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To assess the prevalence of hypothyroidism and hyperthyroidism in the entire cohort of childhood cancer survivors and the therapy related risk factors. Specifically:Part I: 1. To systematically review existing studies on the association between...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON47586

Source
ToetsingOnline

Brief title
SKION LATER Q2008 - Thyroid function

Condition

- Thyroid gland disorders

Synonym
thyroid dysfunction

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, survivor, thyroid functon

Outcome measures

Primary outcome

1) Prevalence of hypothyroidism and hyperthyroidism:

- plasma TSH and Free T4 concentrations

- Anti-TPO (Anti-Thyroxine peroxidase) in survivors at risk, to determine the

percentage of auto-immune hypothyroidism.

material to be stored for determination of anti-TPO for all other survivors

2) Presence of thyroid nodules

- palpation of the neck

3) presence of thyroid carciinoma

- patient chart in addition to palpation of the neck

Secondary outcome

Growth chart (information at 12 mnths, 2 yr and 4 yrs of age)

Height and weight at start of treatment

Parental heights

Start puberty: age menarche (females), age Tanner M2 (from chart), age testis

volume 4 cc (chart)

Use of medication: oral antra-conceptives, anti-epileptics, GH, T4, cortisol,

EE2, testosterone, DDAVP

Previous endocrine deficiencies; if so, what year diagnosed, diagnosed based on

functional tests (chart information)?

Family history: thyroid diseases and family tree

Physical examination:

length (preferably stadiometer) en weight

sitting-height

Tanner stadia

Study description

Background summary

One of the most common sequelae of childhood cancer treatment is damage to the endocrine system. Thyroid hormone is essential for a normal growth and development into adulthood.
In survivors of childhood cancer, primary (thyroidal) hypothyroidism, subclinical hypothyroidism, benign nodules, radiation thyroiditis and Graves* hyperthyroidism followed by hypothyroidism as well as secondary thyroid malignancies have been described following exposure to external cervical and cranial irradiation in. These thyroid pathologies have been described to occur in children and in adults; the incidence is highest in young patients.
Patients who undergo bone marrow transplantation (BMT) are also at high risk of subsequent thyroid dysfunction, with age at BMT and total body irradiation (TBI) as significant risk factors. In a recent study of the Late Effects Surveillance System (Germany) thyroid disorders were found in a number of sarcoma patients treated with chemotherapy without head and neck irradiation. Changes in thyroid function have also been described after treatment with chemotherapy.The exact long term effects of chemotherapy on the thyroid function are, however, still unclear.

Study objective

To assess the prevalence of hypothyroidism and hyperthyroidism in the entire cohort of childhood cancer survivors and the therapy related risk factors.
Specifically:
Part I:

1. To systematically review existing studies on the association between chemotherapeutic agents and thyroid dysfunction among childhood cancer survivors
2. To assess the prevalence of hypothyroidism and hyperthyroidism in the entire cohort of childhood cancer survivors, including a risk factor analysis (for therapy related and other risk factors, such as sex, age at diagnosis, family history etc)
3. To address the role of thyroid dysfunction in relation to other possible late effects (e.g., growth, fatigue, quality of life) among childhood cancer survivors
4. To address the role of genetic factors on thyroid dysfunction among childhood cancer survivors

Part II:
1. To systematically review existing studies on the role of radiation dose from external beam irradiation at the thyroid gland and/or the hypothalamic/pituitary axis and thyroid dysfunction/abnormalities.
2. To review existing laboratory-, animal- and human studies on the impact of TSH - levels on the development of radiation-related thyroid cancer
3. To assess thyroid dysfunction, clinically overt thyroid nodules, and thyroid cancer in the entire cohort of childhood cancer survivors in relation to estimated absorbed radiation dose to the thyroid gland, pituitary gland, and/or hypothalamus
4. To assess the relationship between 131-IMIBG treatments and the risk of thyroid dysfunction/abnormalities

Study design

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, 1481 childhood cancer survivors are at risk of thyroid dysfunction because of radiotherapy including the neck (i.e., thyroid gland, or pituitary-hypothalamix axis). In view of patient care guidelines, thyroid funcion will be assessed for clinical purposes. In addition, 400 control subjects treated with chemotherapy and 400 controls treated with surgery from the same cohort who are not at risk for thyroid dysfunction will be will be asked to participate in this study. For them, the measurements of thyroid function are research-based.

Study burden and risks

The extent of burden will be minimized for all participants of the study.
For survivors at risk for thyroid disorders the vena puncture is part of patient care.
For the controls, the vena puncture is research based.
If abnormalities of the thyroid function are found, the survivor will be sent to the (pediatric) endocrinologist for further follow-up and, if necessary, treatment.

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, 1481 childhood cancer survivors are at risk of thyroid dysfunction because of radiotherapy including the neck (i.e., thyroid gland, or pituitary-hypothalamix axis). In view of patient car guidelines, thyroid funcion will be assessed for clinical purposes. In addition, 400 control subjects treated with chemotherapy and 400 controls treated with surgery (except brain surgery) from the same cohort who are not at risk for thyroid dysfunction will be will be asked to participate in this study. For them, the measurements of thyroid function are research-based.

Exclusion criteria

diagnosis of childhood cancer with survival less than 5 years, age at diagnosis >17 years or diagnosis while residing in foreign country. Patients who had a thyroidectomy will not be eligible for measurement of thyroid function but will be included in the cohort at risk or the control group, to obtain a complete picture of the prevalence of thyroid problems

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2016
Enrollment:	2281

Type:	Actual

Ethics review

Approved WMO Date:	23-01-2015
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:	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	NL34999.018.12