Differentiated thyroid carcinoma in children: Late effects of treatment and pathophysiological background in the Netherlands

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1) To study the late effects of 131-I treatment and TSH suppressive therapy as well as quality of life in patients with childhood-onset DTC. 2) To determine the presence of RET/PTC 1 and 3 translocations and BRAF mutations, and to investigate their…

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

Summary

ID

NL-OMON44899

Source
ToetsingOnline

Brief title
DTC in children

Condition

- Other condition
- Heart failures
- Thyroid gland disorders

Synonym
Differentiated thyroid carcinoma, thyroid cancer

Health condition

kwaliteit van leven

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Stichting Kinderen Kankervrij (KiKa)

Intervention

Keyword: Child, Differentiated thyroid carcinoma, Late effects, Thyroid cancer

Outcome measures

Primary outcome

1) Incidence of late effects of 131-I treatment and TSH suppressive therapy.

2) Presence of somatic mutations and relation with clinical outcome.

Secondary outcome

Postoperative complications.

miRNA (-146b, -181b, -21, -221, -222) expression profile.

Incidence of family members with non-medullary thyroid carcinoma.

Study description

Background summary

Differentiated thyroid carcinoma (DTC) during childhood is an uncommon disease. Children often present with a more advanced tumor stage and show higher recurrence rates compared to adults. Nevertheless, the prognosis of childhood-onset DTC is excellent. The treatment is comparable in children and adults. However, data about long-term effects of 131-I treatment, long-term TSH suppressive therapy and quality of life in pediatric DTC patients are limited. Furthermore, it is not known if there is a relation between the presence of somatic mutations like BRAF and RET/PTC and the clinical course in pediatric DTC patients outside the Chernobyl region. More knowledge on treatment related damage might result in recommendations regarding childhood tailored therapy. Knowledge about the predictive value of the presence of somatic mutations in

thyroid tumors could support the choice of more patient tailored treatment.

Study objective

1) To study the late effects of 131-I treatment and TSH suppressive therapy as well as quality of life in patients with childhood-onset DTC.
2) To determine the presence of RET/PTC 1 and 3 translocations and BRAF mutations, and to investigate their relationship with clinical outcome.

Study design

1. Multicenter cross-sectional study.
2. Follow-up study of the cross-sectional study

Study burden and risks

Burden: 5-year survivors of pediatric DTC will undergo physical examination, blood sampling and will be asked to fill out a general health questionnaire. In addition, in patients aged >=18 years echocardiography, bone mineral density measurement, an electrocardiogram (ECG) and in men semen analysis will be performed at the day of the outpatient clinic visit. Also, these patients will be asked to complete quality of life questionnaires and to wear an (ambulatory) ECG device for 24 hours performing normal daily activities.
Risks: during BMD measurement, patients are exposed to an effective radiation dose below 0.1 mSv. According to the ICRP-62, this study falls into the lowest risk category (I-trivial risk). Therefore, this study is without risk for participants.
Benefit: 5-year survivors will be examined for possible late effects of treatment and will be informed about their health status.

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)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Differentiated thyroid carcinoma diagnosed between 1970 and 2013 at age <= 18 years and treated in the Netherlands.

Exclusion criteria

Not applicable for the study in its entirety because analysis of somatic mutations will be performed in all patients. Late effects are defined as effects occurring >= 5 years after diagnosis. So, evaluation of late effects will only be performed in 5-year survivors. ;Therefore, exclusion criteria are applicable for the following parts of the study:
A. Evaluation late effects including quality of life:
- <5 years since diagnosis
- DTC as a second malignancy
- Thyroid hormone withdrawal or rhTSH <3 months before evaluation;B. In addition to A, for semen analysis:
- Use of drugs that interact with semen quality
- Use of anabolic steroids
- Fever (body temperature >38°C) in the three months before semen analysis;C. In addition to A, for evaluation quality of life:
- Not fluent in Dutch;An exhaustive account based on the inclusion- and exclusioncriteria is provided below 'Aanvullende opmerkingen' ('Additional remarks').

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2012
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-03-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	01-05-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-04-2017

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-10-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28040
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40572.042.12
OMON	NL-OMON28040