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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28040

Source
NTR

Health condition

Differentiated thyroid carcinoma, thyroid cancer, late effects, child

In Dutch:
Gedifferentieerd schildkliercarcinoom, schildklierkanker, late effecten, kind

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Stichting Kinderen Kankervrij (KIKA)

Intervention

Outcome measures

Primary outcome

The primary endpoint is the incidence of late effects of 131-I treatment and TSH suppressive

therapy including quality of life.

Secondary outcome

Secondary outcomes are the presence of somatic mutations and relation with clinical outcome, miRNA (-146b, -181b, -21, -221, -222) expression profile, and incidence of family members with non-medullary thyroid carcinoma.

Study description

Background summary

Background of the study:

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.

Objective of the study:

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. In addition, the postoperative complications and the presence of somatic mutations and their relationship with clinical outcome will be assessed.

Study design:

Multicenter cross-sectional study.

Study population:

All patients with childhood-onset DTC (age <19 years) diagnosed between 1970 and 2013 and treated in the Netherlands. About 150 patients are expected to be included in this study.

Primary study parameters:

The incidence of late effects of 131-I treatment and TSH suppressive therapy.

Secundary study parameters:

Presence of somatic mutations and relation with clinical outcome.
miRNA (-146b, -181b, -21, -221, -222) expression profile.
Incidence of family members with non-medullary thyroid carcinoma.

Study objective

Differentiated thyroid carcinoma (DTC) is rare during childhood. Children often present with a more advanced tumor stage compared to adults. Nevertheless, the prognosis is excellent. Data about long-term effects of treatment in pediatric DTC patients are limited. It is not known if there is a relation between the presence of somatic mutations 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 design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Differentiated thyroid carcinoma diagnosed between 1970 and 2013 at age <19 years and treated in the Netherlands.

Exclusion criteria

No exclusion criteria have been established for the study in its entirety. However, for evaluation of late effects including quality of life the following exclusion criteria are applicable:

1. DTC as a second malignancy;

2. <5 years since diagnosis;

3. Thyroid hormone withdrawal or rhTSH <3 months before evaluation;

4. There are additional exclusion criteria for specific parts of the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-05-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44899
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3280
NTR-old	NTR3448
CCMO	NL40572.042.12

Register	ID
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44899

Study results

Summary results
N/A