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

Gepubliceerd: 22-05-2012 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28040

Bron
Nationaal Trial Register

Aandoening

Differentiated thyroid carcinoma, thyroid cancer, late effects, child

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Stichting Kinderen Kankervrij (KIKA)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is the incidence of late effects of 131-I treatment and TSH suppressive therapy including quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2012
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44899
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3280
NTR-old	NTR3448
CCMO	NL40572.042.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44899

Resultaten

Samenvatting resultaten
N/A