The THYRO-Dynamics study: Is the dynamics of thyroid hormones during cancer treatment in children adaptive or disruptive? - a prospective evaluation

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This prospective evaluation of the dynamics of thyroid hormones during cancer treatment in children is designed to determine the prevalence of thyroid hormone deficits at diagnosis, during and directly after treatment and to study changes in thyroid…

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

Summary

ID

NL-OMON49298

Source
ToetsingOnline

Brief title
The THYRO-Dynamics study

Condition

- Thyroid gland disorders

Synonym
hypothyroidism, non-thyroidal illness, Thyroid dysfynction

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie

Source(s) of monetary or material Support: Stichting KIKA

Intervention

Keyword: Childhood cancer treatment, Thyroid dysfunction

Outcome measures

Primary outcome

1. Prevalence of hypothyroidism (% of study cohort) defined as TSH > reference interval (5.0 mU/L) at the four time points

2. Severity of hypothyroidism at the 4 time points defined as:

- Mild (TSH> 5, FT4 within the reference ranges)

- Moderate (TSH > 10 mU/L, FT4 within reference ranges)

- Severe (TSH above 10 mU/L, FT4 < reference ranges)

Secondary outcome

1. Prevalence of non-thyroidal illness (% of study cohort) defined as FT4 < reference range in combination with elevated rT3 level) at the four time points.

2. Severity of non thyroidal illness at the four time points defined as:

- Mild (FT4 9-10 pmol/L)

- Moderate (FT4 7-9 pmol/L)

- Severe (FT4 <7 pmol/L)

3. The individual changes (delta Δ) of FT4 in pmol/l, TSH in mU/L and rT3 in pmol/l at the 4 time points will be explored.

4. The prevalence of auto-immune disease will be determined by the number of

patients with elevated anti-TPO concentrations (positive defined as: >35 U/mL

(ELiA)).

Study description

Background summary

Endocrine dysfunction is increasingly reported as side effect of upcoming new cancer drugs. Chemotherapy may influence thyroid hormone concentrations due to direct thyroid gland damage (disruptive) or as a consequence of an adaptation mechanism of the body to illness (adaptive). Low thyroid hormones in children may cause fatigue, growth or mental retardation, constipation, or have cardiovascular consequences. There is however, hardly any information on the dynamics of thyroid hormones during chemotherapy in children. For these reasons, there is need for knowledge upon the prevalence and magnitude of thyroid disturbances in this population.

Study objective

This prospective evaluation of the dynamics of thyroid hormones during cancer treatment in children is designed to determine the prevalence of thyroid hormone deficits at diagnosis, during and directly after treatment and to study changes in thyroid hormone metabolism during cancer treatment in children.

Study design

In this prospective observational study, during a 2-year period, children with a new diagnosis of leukemia, sarcoma, lymphoma or a brain tumor and all children undergoing a stem cell transplantation will be included. Thyroid function will be monitored at 4 time points. Prevalence, severity and individual changes of thyroid function will be determined.

Study burden and risks

The burden or risk for the patients is considered as minimal as the blood will be drawn at time points that the children would have had blood drawn also for other reasons. Furthermore for clinical practice already every 3 months questionnaires are being administered via a website (www.hetKLIKt.nu), which is implemented in a web-based method in the Princess Máxima Centre with electronic patient reported outcomes that give a clear overview of the quality of life of pediatric oncology patients and their parents. This portal can also be used to

administer questionnaires for research online. Patients included in this study will not visit the Princess Maxima Center more often during this study because of study purposes.

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

Children (< 21 years) who are diagnosed with leukemia, sarcoma, lymphoma or brain tumor and all children undergoing a stem cell transplantation in the period 2019-2021 in the Princess Máxima Center will be evaluated for inclusion.

Exclusion criteria

- Patients known with previous thyroid disease and receiving thyroid hormone substitution therapy
- Patients diagnosed with Down Syndrome or Cowden syndrome
- Patients known with or suspicious for MEN I or II syndrome
- History or neck radiation or MIBG treatment
- Diagnosis of pituitary tumor, craniopharyngioma

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-01-2020
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	22-10-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL68860.041.19