The incidence of (para) thyroid disorders ten years after the introduction of a new thyroid protection during 131I-MIBG treatment in children with neuroblastoma

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Long-term evaluation of thyroid disorders (TSH elevation and the occurrence of thyroid nodi/carcinoma) in survivors of childhood NBL who received KI, methimazole and thyroxine as thyroid protection during 131I-MIBG exposure. Investigation of the...

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

Summary

ID

NL-OMON37078

Source
ToetsingOnline

Brief title
(Para)-Thyroid damage after 131I-MIBG treatment

Condition

- Thyroid gland disorders

Synonym
Hypothyroidism, thyroid dysfunction, thyroid nodules

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 131I-MIBG treatment, Hypothyroidism, Radio-iodine, Thyroid nodules

Outcome measures

Primary outcome

Thyroid dysfunction (TSH and FT4) and the occurrence of thyroid

nodules/carcinoma. Thyroid dysfunction is defined as having TSH > 4.5 mU/L or

using T4 at the last moment of follow-up.

Secondary outcome

Incidence of hyperparathyroidism and the occurrence of adenomas in the

parathyroid glands.

Study description

Background summary

During treatment with 131I-Meta-iodobenzylguanidine (MIBG) for childhood neuroblastoma (NBL) the thyroid gland may be damaged by exposure to radio-iodine. For this reason, in Emma Children*s Hospital, up to 1999, the thyroid gland during treatment with 131I-MIBG was protected against uptake of $131I^-$ by the administration of potassium-iodide (KI). Despite this protection, a high incidence of thyroid dysfunction was found (in 56 % of survivors an elevated thyrotropin (TSH) concentration) and in a high percentage of the scintigraphic images (21%) uptake of radio-iodide in the thyroid was seen.For this reason, from 1999, a new thyroid protection was introduced, consisting of KI, methimazole and thyroxine (Dilute, Block and Replace = DBR). After a period of two years, in 2001, the new thyroid protection resulted in a decreased occurrence of TSH elevations (17 %) and a decreased number of visible thyroid glands on the scintigram (5 %). It has now been more than 10 years ago that the DBR protection was introduced, but it*s efficacy has never again been evaluated. Unfortunately, recently, two NBL survivors have been diagnosed with

papillary thyroid carcinoma; both had received treatment with 131I-MIBG, one was given KI protection and the other DBR. As the prevalence of thyroid disorders after exposure to irradiation increases with time, we must re-evaluate the incidence of thyroid problems in the children ten years after introduction of the new DBR prophylaxis. Furthermore we will check for hyperparathyroidism and or the occurrence of parathyroid adenomas in all survivors, since this has been described after MIBG treatment. In addition we will evaluate linear growth and pubertal development in the survivors, given that small stature and late puberty have been described after NBL treatment.

Study objective

Long-term evaluation of thyroid disorders (TSH elevation and the occurrence of thyroid nodi/carcinoma) in survivors of childhood NBL who received KI, methimazole and thyroxine as thyroid protection during 131I-MIBG exposure. Investigation of the incidence of hyperparathyroidism and or the occurrence of parathyroid adenomas.

Study design

Prospective cohort study

Study burden and risks

There is no risk for the patients. During a routine vena puncture for other reasons, also blood with be withdrawn for measuring of thyroid function. Thyroid ultrasonography is not painfull and will last only 15 minutes. If a thyroid nodule is found, the patient will be referred to the pediatric endocrinologist for further diagnostics according to routine patient care.

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

All neuroblastoma patients treated with 131I-MIBG, in the period 1999 until 2011 (who received the DBR profylaxe for thyroid protection) in Emma Children*s Hospital and Sophia Children*s Hospital will be evaluated and included in the study

Exclusion criteria

All neuroblastoma patients who were not treated with 131I-MIBG .

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	19-02-2013
Application type:	First submission
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	NL41141.018.12