The incidence of thyroid dysfunction in children who have been given diagnostic 123I-MIBG for suspected neuroblastoma.

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To evaluate the occurrence of thyroid dysfunction children and young adults with NB and other childhood malignancies , who received diagnostics with 123I-MIBG

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

Summary

ID

NL-OMON41559

Source
ToetsingOnline

Brief title
Thyroid function after the use of diagnostic 123I-MIBG

Condition

- Thyroid gland disorders

Synonym
Hypothyroidism, thyroid dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KIKA

Intervention

Keyword: MIBG, Radiation, Radio-iodine, Thyroid

Outcome measures

Primary outcome

The end-points are TSH, FT4.

Secondary outcome

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Study description

Background summary

The specific uptake and accumulation of 123I-MIBG and 131I-MIBG by neuro-ectodermal tissues makes the compound suitable for diagnostics and treatment of neuroblastoma (NB). A drawback of this treatment is that I^- is cleaved off from the administered radioMIBG and will be taken up by the thyroid; reason to protect the thyroid. It was found that, despite protection, thyroid dysfunction and thyroid nodules may occur. During diagnostics with 123I-MIBG the thyroid gland is also protected. We do not know, however, whether 123I-MIBG is also harmful for the thyroid gland.

Study objective

To evaluate the occurrence of thyroid dysfunction children and young adults with NB and other childhood malignancies , who received diagnostics with 123I-MIBG

Study design

In the outpatient clinic of the pediatric oncology and the PLEK-poli (Late Effects Study group), all patients who have received diagnostic radio-MIBG will be asked to participate. During a routine vena puncture for other reasons, also blood with be withdrawn for measuring thyrotropin, free thyroxine and anti-thyroperoxidase antibodies.

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 During a routine vena puncture for other reasons, also blood with be withdrawn for measuring of thyroid function.

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 and young adults who received diagnostic 123I-MIBG for suspected neuroblastoma

Exclusion criteria

Children and young adults who received therapeutic 131I-MIBG

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	04-03-2013
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	NL38114.018.12