Catecholamine metabolites and their correlations with biological and clinical features in patients with neuroblastoma

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Main aim:Identify the optimal urinary catecholamine metabolites panel for neuroblastoma diagnostics.Sub-aims:1. Investigate whether catecholamine metabolites can also be linked to prognosis and thus assist in risk assessment.2. Investigate whether…

Ethical review	Approved WMO
Status	Will not start
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON45532

Source
ToetsingOnline

Brief title
Catecholamine metabolites in patients with neuroblastoma

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Neuroblastoma

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: Stichting Villa Joep

Intervention

Keyword: Catecholamines, Diagnostics, Neuroblastoma, Prognosis

Outcome measures

Primary outcome

- Urine and plasma catecholamine metabolites levels

- Patient characteristics: age and gender

- Tumor characteristics: stage, cytogenetics (such as MYCN amplification, LOH

1p, LOH 11q, ALK), MIGB-scan, bone marrow invasion, risk group, MRD

-Clinical outcomes (prognosis): primary response to therapy (conform INRG),

event-free survival and overall survival

Secondary outcome

Not applicable

Study description

Background summary

Neuroblastoma is the most common extracranial solid tumor in childhood. Besides pathology (diagnostic golden standard), urinary catecholamines (VMA and HVA) are measured as part of the diagnostic work-up and monitoring response to therapy/follow-up. After the diagnosis has been established, the patient is allocated to a risk-group and treated accordingly. Current risk-group stratification (low-, intermediate- and high risk) is based on clinical parameters (metastatic disease), pathological and genetic factors, such as MYCN amplification. In all risk groups, patients with the same risk assessment, and thus receiving the same treatment, can have markedly different outcomes. Therefore, additional markers that can distinguish low and high risk disease more accurately are needed. Furthermore, these markers might also assist in therapy monitoring and early detection of relapse/progression.

In 90-95% of neuroblastoma patients, the urinary concentrations of catecholamine metabolites are strongly elevated and provide an important non-invasive diagnostic tool for diagnosis, during treatment and at follow up.

Our retrospective study showed that implementation of a panel of 8 catecholamines, instead of only VMA and HVA, improves diagnostic sensitivity by 10%. Furthermore, 1 of the catecholamines also correlated with high-risk disease and thus with clinical outcome. For this reason, in this project we intend to prospectively validate these findings in order to improve standard care (diagnostics and risk-group allocation).

Study objective

Main aim:
Identify the optimal urinary catecholamine metabolites panel for neuroblastoma diagnostics.

Sub-aims:
1. Investigate whether catecholamine metabolites can also be linked to prognosis and thus assist in risk assessment.
2. Investigate whether catecholamine metabolites can be used for monitoring response to therapy and possible progression/relapse
3. Determine which medium (urine or plasma) is the most accurate for catecholamine metabolites measurement.

Study design

Prospective study of catecholamine metabolites (dopamine, 3-methoxytyramine, norepinephrine, normetanephrine, epinephrine, metanephrine, HVA and VMA) in urine of every newly diagnosed neuroblastoma patient. Measurements will be done at certain points during the clinical course (e.g. at diagnosis, before and after surgery, etc.).

Furthermore, a pilot-study will be done based on 20 patients. In this study, the urinary catecholamine metabolites will be compared to their corresponding plasma levels. If the plasma catecholamine will be as sensitive/more sensitive than the urine catecholamine, the study cohort will be increased to the complete urine cohort.

Study burden and risks

Urine: no burden, it's part of the standard diagnostics (only the metabolites panel is broader)
Plasma: blood will be collected as part of routine diagnostics. During these moments, when possible, 1 additional will be taken.

Contacts

Public
Prinses Máxima Centrum voor Kinderoncologie

Lundlaan 6
Utrecht 3508 AB
NL
Scientific
Prinses Máxima Centrum voor Kinderoncologie

Lundlaan 6
Utrecht 3508 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. Suspected neuroblastoma patient
2. Urine sample must be available from the moment of diagnosis
3. Histologically proven neuroblastoma

Exclusion criteria

1. Not neuroblastoma

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL58779.041.16