The evaluation of the cerebellar symptoms in patients with opsoclonus myoclonus syndrome diagnosed and treated at the Sophia*s Children*s hospital

Published: 06-03-2018
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The objective of the study is to evaluate the cerebellar symptoms in children with OMS diagnosed and treated at the Sophia Children*s Hospital.

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system infections and inflammations
Study type	Observational non invasive

Summary

ID

NL-OMON47850

Source
ToetsingOnline

Brief title
Evaluation of long term sequelae and treatment outcomes in OMS

Condition

- Central nervous system infections and inflammations

Synonym
Dancing-eyes-and-feet syndrome, Opsoclonus Myoclonus Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Long term sequelae, Opsoclonus Myoclonus Syndrome, Treatment outcomes

Outcome measures

Primary outcome

The study will have multiple endpoints:

* Computer-assisted assessments:

- Eye tracking: smooth pursuit and saccades;

- Balance plate: scatter in center-of-gravity;

Secondary outcome

* Clinical endpoints

- OMS rating scale score;

- SARA-score.

* Computer-assisted assessments:

- Score *Shelby*s Quest*.

* Questionnaires;

Study description

Background summary

Most OMS patients have residual symptoms, despite aggressive treatment. Due to the probable involvement of the cerebellum, elaborate cerebellar testing may give a precise assessment of the disease activity. These assessments may be a valuable tool in the clinic, as they may be used as a guideline to intensify or

alter current treatment.

Study objective

The objective of the study is to evaluate the cerebellar symptoms in children with OMS diagnosed and treated at the Sophia Children*s Hospital.

Study design

A cross-sectional study

Study burden and risks

not applicable

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

All patients with OMS, diagnosed and treated at the Sophia Children*s Hospital will be included. OMS is defined as the presence of *3 of the following symptoms: [1] opsoclonus, [2] myoclonus and/or ataxia, [3] behavioural change and/or sleep disturbance and [4] neuroblastoma.
Age-matched children with pilocytic astrocytoma, diagnosed and treated at the Sophia Children*s Hospital will be included.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Insufficient command of the Dutch language (spoken and/or written)
- Age above 12 years
Children with pilocytic astrocytoma will be excluded from participation, when they were treated with radiotherapy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	06-03-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL60317.078.17