FASTigial: Finding Anatomical SubsTrates of neuropsychological outcome in children with posterior fossa tumors (add-on project on the European CMS study)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON56713

Source
ToetsingOnline

Brief title
FASTigial study

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system, skull and spine therapeutic procedures

Synonym
Cerebellar Mutism Syndrome, unable to speak after brain surgery

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: Ministerie van OC&W,funding Kika grant

Intervention

Keyword: cerebellum, mutism, neurosurgery, posterior fossa

Outcome measures

Primary outcome

The primary aim is to investigate early clinical and neuroradiological predictors of neuropsychological outcome in children with posterior fossa tumors.

Hypothesis: clinical criteria, CMS symptom severity, and changes inneuroradiological findings over time will predict neuropsychological outcome at 12 months after surgery. For example, youngerage, greater CMS symptom severity, and larger changes in white matter metrics (DTI) and cerebral perfusion (ASL) over time will be associated with poorer neuropsychological outcomes.

Secondary outcome

Secundary objectives are to identify group differences and changes over time in neuroradiological and neuropsychological measures for children who have higher versus lower CMS symptom severity.

Hypothesis: patients with higher versus lower CMS symptom severity will have greater pre- and post-surgery damage to the efferent cerebellar pathways (DTI),

leading to cerebello-cerebral diaschisis and supratentorial hypoperfusion

(ASL). We expect that some neuroradiological deficits will be shown at the

pre-surgery phase, but impairments will become more apparent post-surgery. Some

children will show recovery over time; however, those with greater CMS symptoms

will have slower recovery.

Study description

Background summary

Central nervous system (CNS) tumours constitute 25% of all childhood cancers, and more than half of these are located in the cerebellum. One of the most troublesome late effects after operation for such a tumour is the cerebellar mutism syndrome (CMS) which is seen in up to 25% of children after surgery. It is characterized by mutism, hypotonia, ataxia and irritability, and the exact causes have yet to be identified. Although a cure may have been achieved with respect to their brain tumour, the CMS and its consequences can still represent a lifelong challenge for these children. Since roughly half of all paediatric brain tumours reside in the posterior fossa and require operative removal, the CMS constitutes both a common and severe problem in paediatric neurooncology.

Study objective

The purposes of this study are to uncover

- Which clinical and neuroradiological measures can be used to predict the (neuropsychological) outcome and progression of symptoms in children with CMS?

We hope that the results will contribute to an overall reduction in incidence and severity of the CMS as well as increasing understanding and awareness of the syndrome. Furthermore, this study can lead to harmonization of the treatment of these patients.

Study design

Multicenter prospective observational cohort study

Study burden and risks

Patients participating in the study will be treated according to local standards. Additionally, we will conduct neuropsychological tests preoperatively, postoperatively, and 12 months after surgery using digital tests that take approximately 30 minutes each time. While the child completes the neuropsychological tests under supervision, the parent(s) will be asked to digitally complete several questionnaires. Furthermore, the child will undergo an MRI scan as part of standard care. The preoperative, postoperative, and 12-month follow-up MRI scans will also be used for the study. Only 12 months after the operation, 2 additional MRI sequences will be added to the clinical protocol, extending the MRI duration by 5-15 minutes.

Participation in the study will not impact or interfere with the child's treatment plan. The child will not experience any additional benefit or risk.

Cerebellar Mutism Syndrome (CMS) predominantly occurs in children. There are few case reports of CMS in adults in the literature. Therefore, it would not be possible to conduct this study with adult patients.

Besides contributing to an increased understanding and awareness of the CMS this study has the direct prospect of reducing both the incidence and the severity of the syndrome, which would be a great advantage for other children with CMS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Eligible for European CMS study
- Age 2-18 years at the date of first imaging showing this tumour
- Understanding and speaking of Dutch language by patient and/or parents

Inclusion criteria European CMS study:
- Age <18 years at the date of first imaging showing this tumour
- Tumour in the cerebellum/4th ventricle/brainstem with intention to treat with surgical resection or open biopsy.
- Signed Informed consent from custodial parent(s) and/or patient

Exclusion criteria

- Patients who have had previous surgery of the posterior fossa
- No informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-08-2024
Enrollment:	80
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	03-04-2024
Application type:	First submission
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
ISRCTN	ISRCTNnumbertobeconfirmed
CCMO	NL85971.041.23