Childhood brain Cancer, InSight in Sight; New EXpertise on Tailored ophthalmological follow up in a prospective nationwide study in the Netherlands

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Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57205

Source
ToetsingOnline

Brief title
CCISS Next study

Condition

- Vision disorders
- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Visual decline, visual impairment

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Fischer Stichting;Rotterdamse Stichting Blindenbelangen;Janivo Stichting

Intervention

Keyword: Brain tumor, Children, Ophthalmological examination, Optical coherence tomography (OCT)

Outcome measures

Primary outcome

The primary outcome measures are visual acuity (logMAR), visual field (results of age-specific visual field test) and changes in OCT parameters (RNFL thickness and GCL-ILP).

For further information please refer to the study protocol, chapter 8 (page 18-24).

Secondary outcome

Secondary study parameters include measurements of OCT parameters (RNFL thickness and macular GCL-IPL thickness) at baseline and at 4-5 years after diagnosis.

Tertiary outcome parameters include baseline characteristics as age, gender, ethnicity, medical (including ophthalmologic) history, neurofibromatosis 1 (yes/no), brain tumor type (histology), tumor location, tumor size and presence/absence of hydrocephalus and/or metastases.

The last outcome of this CCISS Next study is the long-term (4-5 years after diagnosis) quality of life in relation to the visual (visual field testing, visual acuity and OCT), medical (type of brain tumor and treatment) and sociodemographic (age, sex) variables. We will assess generic and cancer-specific health-related quality of life (PedsQL), as well as vision-related quality of life (PAI-CY/PAI-YA).

For further information please refer to the study protocol, chapter 8 (page 18-24).

Study description

Background summary

In the Netherlands, about 140 children per year are diagnosed with a brain tumor. Due to improvements in diagnostics and treatment options of childhood brain tumors, the 5-year survival rate is about 80% in developed countries. As survival rates have increased in recent years, it is important to better understand the long-term effects of a brain tumor and its treatment. Visual impairment is one of these effects and can be caused by compression of the tumor on brain tissue/nerves or obstruction of cerebrospinal fluid. However, visual impairment can also occur as a complication of various treatments, such as neurosurgery, radiotherapy or chemotherapy. Vision loss can affect a child's development and can markedly affect quality of life.

The previous CCISS study has shown that visual impairment is present in 79% of children with a brain tumor at diagnosis. However, it is not known how vision continues to develop during and after brain tumor treatment. In addition, ophthalmologic examinations are performed differently in each center and many ophthalmic tests are available, making outcomes difficult to compare.

Previous research has shown that optical coherence tomography (OCT) may be of additional value for early detection of optic nerve damage in children with a brain tumor. However, it is not known whether OCT at diagnosis can be predictive of long-term visual outcome. In addition, little is known about the

course of OCT parameters in children treated for a brain tumor.

Study objective

1. Primary objective:
The primary aim of this study is to investigate the predictive value of OCT parameters at diagnosis for long-term (4-5 years after diagnosis) visual impairment (visual acuity, visual field) in children with a primary brain tumor.

2. Second objective:
The secondary aim of this study is to describe the longitudinal change of OCT parameters (RNFL, GCL-IPL) in children with a brain tumor.

3. Third objective:
The third aim of this study is to enlarge insight in long-term (4-5 years after diagnosis) development of visual impairment in children with different types of brain tumors, location of the tumor, age and given treatment modalities, to provide patient-centered information and personalized ophthalmological follow up for children with a brain tumor.

4. Fourth objective:
To evaluate long-term (4-5 years after diagnosis) health-related and vision-related quality of life and the relation to visual (visual field testing, visual acuity and OCT), medical (type of brain tumor and treatment) and sociodemographic (age, sex) variables.

Study design

The CCISS Next study is a subsequent study on the nationwide, prospective, observational cohort CCISS study in the Netherlands. This multicenter study is embedded in the University Medical Center Utrecht (UMCU) in association with the Princess Máxima Center for pediatric oncology. The care and follow-up of children with a brain tumor is centered at the Princess Máxima Center in the Netherlands, providing a complete overview of a complete cohort of children with brain tumors.

The following centers in the Netherlands will participate in the CCISS Next study:
- University Medical Center Utrecht;
- Princess Máxima Center for Pediatric Oncology Utrecht.

Study design:
Nationwide prospective observational study. The study includes one cohort with a longitudinal design.

Study setting:

Outpatient

Duration of study:
The duration of this study is 36 months. All included patients will be followed for a period of 48 to 60 months (+/- 6 months) after inclusion in the previous CCISS study.

Study burden and risks

Children with a brain tumor have a considerable risk of irreversible impaired vision due to high intracranial pressure, tumor tissue pressing on the optic pathway and eye movement disorders, either at diagnosis or during the course of their treatment and follow up. It is reported that the harmful influence of the tumor or its treatment on visual functioning, have a great impact on the general psychomotor development, school participation, further educational or social achievements and participation later in life. Moreover, visual loss due to a brain tumor is often irreversible. Visual dysfunction should be detected as early as possible, preferably before it has resulted in persistent and irreversible visual loss.
Studies have shown that early detection of visual loss in some cases can lead to improvement in visual outcomes.

Currently, the selection of the most accurate testing methods for detecting visual decline per age and type of brain tumor are still inconsistent. An optimization of testing methods is necessary if we want to detect early changes in visual function and preserve visual function. Preliminary results have shown that OCT, in addition to other ophthalmological tests (VA or VF testing) can serve as an objective and consistent method for monitoring visual decline. However, there are no studies available describing the predictive value of OCT at diagnosis on long-term visual outcome when children have been treated for a brain tumor.

The information obtained by this study and the additional investigation (OCT-scan) will enable us to gather information about the longitudinal changes of OCT in children with a brain tumor. Furthermore, this study will provide information about the relation between the course of visual decline, disease status and type of treatment in children with a brain tumor.

This study is designed to follow up the unique cohort of children with a brain tumor included in the first CCISS study. Brain tumors are mostly found in children. Furthermore, various aspects of the visual system are not yet fully developed in young children. For example, normal VA improves with age, most dramatically in the first 24 months of life, followed by a consistent phase of slower improvement continuing up to 72 months and likely beyond. Therefore it is important to analyze the results obtained from this study from different age groups.

The risk of the additional investigation are negligible and the patient burden appears minimal. Making a handheld/tabletop OCT scan is a non-invasive procedure, which takes approximately 5-10 minutes to perform. Prior to the handheld OCT, mydriatic eye drops will be administered for pupil dilatation. The use of mydriatic eye drops in children is considered to be safe. Mydriatic eye drops used in this study are also administered during regular ophthalmologic follow up of children.
Visual acuity and visual field examinations are performed at regular ophthalmic follow up times of children with brain tumors. For the children who no longer undergo ophthalmic follow up, this CCISS Next study means that they will undergo an additional one-time ophthalmic check-up.
All of the examinations conducted within the CCISS Next study were also performed previously within the CCISS study.

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)

Inclusion criteria

- Participation in the previous CCISS study (NL67799.041.18)
- Indicated during the earlier KIZZ study that it was agreed to approach the patient for follow-up research
- Informed and having given informed consent (either by the patient and/or parents/legal guardian)

Exclusion criteria

- Refusal by patiënt and/or parent(s)/legal guardian
- If the child has not previously had monitoring as part of the CCISS study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	27-12-2024
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
CCMO	NL86284.041.24