A visual-developmental perspective for children born very preterm

Published: 19-04-2017
Last updated: 11-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON45406

Source
ToetsingOnline

Brief title
Visual perspective for very preterm children

Condition

- Vision disorders
- Neurological disorders of the eye
- Neonatal and perinatal conditions

Synonym
cerebral visual impairment, visual processing dysfunctions

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NOVUM (stichtingnovum.org)

Intervention

Keyword: children born very preterm, visual assessment, visual processing, visual rehabilitation

Outcome measures

Primary outcome

Parameters that serve as a quantification of visual processing functions, such as visual function exams and visually-guided orienting behavior (viewing reaction times and accuracy). Endpoints are the changes in these parameters after the visual rehabilitation program (i.e. from 2 years CA).

Secondary outcome

Medical and demographic characteristics

Neurocognitive development at 2 years of age

CVI Inventory for daily life visual functioning

Parental interview to evaluate experiences with and ethical issues of the new care chain

Study description

Background summary

In the Netherlands, 20.000 children are born preterm each year (i.e. before 37 weeks of gestation). Over the years, their survival rates have increased due to the intensive, high quality care that they received. As a consequence, the number of children that sustains neurological damage has increased as well. Because about 40% of the brain is involved in visual information processing, there is a high chance that preterm children will develop problems in the visual domain (e.g., visual sensory, oculomotor or visual perception problems). Visual processing problems are known to have an adverse effect on development in other domains, such as cognitive outcome at school age.
Despite the advanced medical diagnostic techniques that are available to detect brain damage early in life, the detection and classification of visual

processing problems at a young age is challenging. Subtle deficits in connectivity at a microstructural level are not detected with conventional imaging methods. In addition, the nature and degree of structural damage is not always related to the functional visual consequences. Moreover, before the corrected age (CA) of 4-5 years the functional consequences, or the efficiency of visual processing, can be challenging to assess without verbal communication. Yet, the sooner visual rehabilitation programs can start, the higher the chances are that they will enhance visual processing development given the high levels of brain plasticity early in life.
Recently, a new method based on eye tracking measurements of viewing behavior has shown promising results for assessing the efficiency of visual processing in a nonverbal manner in children born preterm (Pel et al., 2016). It was shown that children born preterm are at high risk of visual processing delays (VPD). These VPD are known to be strongly correlated with brain damage-related visual problems (cerebral visual impairment; CVI). The early and nonverbal assessments open up the possibility to monitor or even rehabilitate VPD in these children at a young age. Current visual rehabilitation programs are focused on stimulating functional visual processing and viewing behavior in different visual domains (e.g., color, motion, contrast). To date, the effectiveness of such visual rehabilitation programs for children younger than 4 years has not yet been investigated. Using the eye tracking-based method, the effectiveness of rehabilitation programs in terms of the efficiency and quality of visual processing can be examined in children born very preterm.

Study objective

The main objective of this study is to investigate the effectiveness of early visual assessment and early rehabilitation of VPD in very preterm children (born <30 weeks GA), from 1 year CA.

Study design

Randomized controlled intervention study (RCT) integrated with standard clinical care.
First, preterm children undergo a visual screening from 1 year CA. They are classified as being at risk of VPD when they show abnormal viewing behavior, i.e. delayed or incorrect gaze responses compared to age-matched controls. The children at risk of VPD will be referred to Visio where they receive standard care: a visual function assessment and a visual rehabilitation program. Children are randomly allocated to a direct intervention group (starting upon inclusion), or a control intervention group (starting 1 year after inclusion). The control group will also receive intervention, but with a delay of one year. During this year they will receive general developmental support and monitoring, without specific visual components. This means that all children will receive visual rehabilitation at an earlier age than is currently the case (i.e. <4 years), while at the same time the reliability of an RCT is ensured.

After 1 year, the effectiveness of early visual rehabilitation will be examined with follow-up visual and neurocognitive assessments. In addition, differences in effectiveness of direct and postponed early visual rehabilitation are assessed.

Intervention

The intervention involves a visual rehabilitation program that is part of standard clinical care for children at Royal Dutch Visio and that consists of visual training and visual stimulation. The visual rehabilitation consist of a general protocol (standardized and similar for all children) and a supplement protocol (adapted to the specific VPD of the child). The programs will be performed by experienced behavioral therapists in the child*s home environment and will be done once a week, for a total duration of 9 months. Rehabilitation will be provided to all children at risk of VPD, only the age at which it starts differs depending on RCT allocation (i.e. upon referral at 1 year CA, or one year later at 2 years CA).

Study burden and risks

The risks associated with participation are negligible and the burden for the children is minimal.
Apart from the visual screening at 1 year CA, the total program is standard care for children with (suspected) visual problems. Only the age at which this care is applied is advanced for this study. The visual screening that all children undergo consists of an eye tracking assessment, during which children watch a computer screen without receiving instructions. For the children at risk of VPD the use of eye drops during the orthoptic exam may cause a slight burden, however, this is standard care and monitored by an ophthalmologist. The additional visual assessments and the rehabilitation program are non-invasive and non-restrictive, and part of standard clinical care. The study is group-related since it involves detecting and rehabilitating VPD in a high-risk group: children born (extremely) preterm. Benefits for all preterm children are earlier assessments and, if applicable, earlier rehabilitation of a risk of VPD than is the case in conventional pediatric care (i.e. from 1-2 years CA instead of ~4 years CA).
Unanticipated results with regard to visual functioning of children in the control group will be communicated with parents.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patient group: All infants who have been born extremely or very preterm (i.e. before 30 weeks gestational age) at the NICU of the Erasmus MC-Sophia Children*s Hospital will be available for inclusion at 1 year corrected age.
Control group: children who were born at term and who have no record of visual or neurological problems will be available for inclusion from 1 year of age

Exclusion criteria

All groups: Visual acuity below 0.05 (Snellen equivalent) / High chance of epileptical activity during assessment
Patient group: Retinopathy of prematurity (ROP) of grade 3 or higher

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	19-04-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-12-2017
Application type:	Amendment
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	NL60145.078.16