Blik Vooruit: visuele screening en revalidatie bij te vroeg geboren kinderen

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1. An early screening at 1y of corrected age will identify preterm children with an increased risk of developing visual processing dysfunctions 2. Early visual rehabilitation from 1y of corrected age will benefit the visual and neurocognitive...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20047

Bron
NTR

Verkorte titel
VIPP

Aandoening

visual processing dysfunctions
visual attention dysfunctions
prematurity

Ondersteuning

Primaire sponsor: Erasmus Medical Center. Erasmus MC-Sophia, Royal Dutch Visio
Overige ondersteuning: Stichting NOVUM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Visual assessment (eye tracking-based)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: 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.

A combined approach of detecting and rehabilitating VPD in children born preterm requires the expertise of neonatologists (Sophia Children’s hospital) and of professionals working at visual rehabilitation centers (Royal Dutch Visio). Ultimately, our goal is to monitor and support the preterm child with (a risk of) VPD from birth onwards.

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 yearly undergo a visual assessment from 1 year CA. Within the first year, they can be 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, and/or evidence for structural damage in visual brain areas. 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). In the first year, the control group will receive general developmental support without specific visual training components. This group will start the visual intervention with a delay of one year. 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.

Doel van het onderzoek

1. An early screening at 1y of corrected age will identify preterm children with an increased risk of developing visual processing dysfunctions

2. Early visual rehabilitation from 1y of corrected age will benefit the visual and neurocognitive development of preterm children with a high risk of visual processing dysfunctions

Onderzoeksopzet

baseline (at 1y or 2y corrected age), 3-monthly follow-up, 1-year follow-up (at 2y or 3y corrected age)

Onderzoeksproduct en/of interventie

Visual rehabilitation program

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- born before 30 weeks of gestation

- patient at Erasmus MC - Sophia, dept Neonatology

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Visual acuity below 0.05 (Snellen equivalent)

High chance of epileptical activity during visual assessment

ROP of grade 3 or higher

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	20-04-2017
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6622
NTR-old	NTR6952
Ander register	METC Erasmus MC : 2016-724

Resultaten