The effect of acquired brain dysfunction on visuomotor integration in neonatal critically ill children

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Do neonatal critically ill children aged 9-16 years have problems with visuomotor integration? If yes, which aspects of the visuomotor integration are affected and require a possible intervention?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and hereditary disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON46243

Source ToetsingOnline

Brief title Visuomotor integration after neonatal critical illnes

Condition

- Congenital and hereditary disorders NEC
- Neurological disorders NEC
- Neonatal and perinatal conditions

Synonym anatomical congenital malformation, neonatal critical illness

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: eye-hand coordination, neonatal, neuropsychological assessment, visuomotor integration

Outcome measures

Primary outcome

Parameters to quantify eye- and hand movements, such as the reaction time and

velocity of eye-hand movements, and the accuracy of both movements.

Secondary outcome

Motor performance-test

Parents perceived motor competence of their child-checklist

Participation of the child

Motor competence (child)

Sustained attention of the child

Motor-free Visual Perception Test

Wechsler Intelligence Scale for Children-3-NL (WISC)

VMI: test of Visual Motor Integration

behavioral symptoms

Study description

Background summary

Critically ill new-born babies can in the long term develop mental and/or motor problems, even when they are born at term. Recently, it has been shown that when these children reach school age, they often have problems with ball skills. It seems that these children have acquired some form of brain dysfunction due to critical illness, treatment in intensive care, and the need for surgical interventions in the first phase of life. Based on currently available literature on long-term outcomes after neonatal critical illness, our hypothesis is that the acquired brain dysfunction has led to problems with the translation of visual information (e.g. determining the position and speed of the ball) into a goal-directed motor action (i.e. a coordinated eye-hand movement for catching the ball). This process in the brain is termed visuomotor integration (VMI).

Study objective

Do neonatal critically ill children aged 9-16 years have problems with visuomotor integration? If yes, which aspects of the visuomotor integration are affected and require a possible intervention?

Study design

observational study with participants and controls

Study burden and risks

There are recent techniques available to quantitatively assess visuomotor integration. These new techniques offer the possibility to test the efficiency of performing different aspects of catching a ball. However, good norm values for children are not yet available for some specific tasks. For this reason, it is important not only to examine the patients but also healthy controls. For interpretation of the research results, vision is included as a confounding factor. A refractive error or reduced binocular vision - caused by a developmental disorder - can lead to a blurred image or a delayed perception of an image. From our own experiences, children like the neuropsychological, motor and eyetracking tests, but it requires to some extend some effort of the investigators to keep them focussed.

Burden consists of research time (including travelling time this may take one full working day for both children and parents), filling in questionnaires by the parents (can be done while waiting for a next test session), and the use of eye drops prior to the diagnostic ophthalmological examination. Administration of the cycloplegium cyclopentolate 1% may be felt when the liquid is dripped in the eyes and the children may have transient visual problems due to accommodation problems (described at 1-10% according to the Pharmacotherapeutic Compass). There is very little chance of developing an increased intraocular pressure (described at 0.1-1% according to the Pharmacotherapeutic Compass). The procedure of administering a cycloplegium is a routine procedure in diagnostic eye examinations and will be carried out by expert personnel who have experience with this type of procedure and the subsequent ophthalmological examination in children. As a result, the burden will be minimal and outweigh the possible benefits, namely insight into visuomotor integration, for which specific intervention may be possible in due course. A standard intervention is currently not available for this group of children, but if deviations are identified during the study that can be improved with targeted intervention (for example, ophthalmological abnormalities), the participant will be referred for further treatment. In those cases, the participant benefits from participating in the research.

It is of great importance for the current patient population but also for children in other high-risk groups to study the quality of visuomotor integration at a young age by means of specific eye-hand tasks. Restrictions in this area may not only affect ball skills (and therefore success in leisure activities and sports), but also have an impact on other situations in everyday life that must be anticipated in a moving and changing environment. When the problem is discovered at a young age, specific interventions or even rehabilitation can be initiated early in life. This research may lead to the development and evaluation of a targeted intervention that may help future children at risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patient group: children aged 9 to 16 years that have had birth defects, including CDH or OA, and have been treated with or without ECMO. Control group: children without birth defects and/or ECMO treatment

Exclusion criteria

Serious neurological and/or visual co-morbidity. Diagnosed with attention and/or concentration deficits such as AD(H)D

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-12-2018
Enrollment:	70
Туре:	Actual

Ethics review

Approved WMO

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Date:	19-10-2018
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

ID: 26945 Source: NTR Title:

In other registers

Register CCMO OMON ID NL66820.078.18 NL-OMON26945