Comparison of school-age outcome in children with a history of perinatal asphyxia with and without hypothermia therapy with controls

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To study cognitive and behavioral outcome and resting-state dynamics in children with a history of perinatal asphyxia before and after the introduction of hyothermia and to compare these data with a group of controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational invasive

Summary

ID

NL-OMON47459

Source
ToetsingOnline

Brief title
Resting-state fMRI following perinatal asphyxia with or without hypothermia

Condition

- Congenital and peripartum neurological conditions
- Neonatal and perinatal conditions

Synonym
perinatal asphyxia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Stichting Neonatale Neurologie;Vaillant fonds

Intervention

Keyword: hypothermia, perinatal asphyxia, resting-state functional MRI

Outcome measures

Primary outcome

Neuropsychological assessment:

comparison of neurospychological outcome assessed at 9-10 years of age in children who suffered perinatal asphyxia, were treated /or not with hypothermia in the neonatal period

MRI.

Conventional MR imaging will be evaluated for presence of structural abnormalities. From the resting-state fMRI sequence, cross-correlation calculations between resting-state time series of spatially distant brain areas can determine functional connectivity (FC) between brain areas. Next to network localization, network size and FC strength will be studied.

Secondary outcome

MRI

Comparison of cross-correlation calculations between resting-state time series of spatially distant brain areas can determine functional connectivity (FC) between brain areas. Next to network localization, network size and FC strength will be studied in infants with and without perinatal asphyxia.

Comparison of the results of the neuropsychological evaluation with the results

of the test using the virtual reality glasses. .

Study description

Background summary

Children who have suffered from cerebral injury, for instance after perinatal asphyxia (PA), may show signs of impaired neurodevelopment, expressed in behavioral, memory problems or learning disabilities. In children with PA these deficits are also observed when in the neonatal period no significant structural magnetic resonance imaging (MRI) abnormalities are found. Yet, from clinical follow-up it appears that 20 to 25% of these infants without hypothermia therapy encounter problems at school concerning behavior, memory or learning. Therefore, rather than focusing on brain structure, studying functional brain networks in these children by means of resting-state functional MRI (rs-fMRI) may improve understanding why these children have neurodevelopmental impairments and whether those children who have been cooled are doing better, both with regard to their outcome as well as their rs-fMRI. Hypothermia was first introduced in the netherlands in 2008. The technique was implemented by dr F. Groenendaal (UMCU) and is performed in a standard way in all 10 Dutch NICUs.It is hypothesized that different network configurations and lower overall connectivity between resting-state networks in the areas for executive functions are seen in the children that have cognitive and/or behavioral problems.
Furthermore, it may in the near future also be possible to study functional brain networks in these children by means of resting-state functional MRI (rs-fMRI) already in the neonatal period, allowing early prediction of concentration behavioral and memory problems at school age; this would allow early recognition and intervention.

Study objective

To study cognitive and behavioral outcome and resting-state dynamics in children with a history of perinatal asphyxia before and after the introduction of hyothermia and to compare these data with a group of controls.

Study design

This observational study will, after informed parental consent and child assent has been obtained, use prospectively collected data of children with a history of perinatal asphyxia. Standard clinical follow-up of the patients included psychological and motor testing. Children with perinatal asphyxia have been

seen in the follow-up clinic as standard clinical care until the age of 5 years. When participating in the study, children will have a neuropsychological assessment and an MRI including resting-state functional MRI. Resting-state dynamics of these children with perinatal asphyxia, with and without hypothermia, will be compared to data of age-matched, otherwise healthy controls derived from the Youth study (http://youthonderzoek.nl/)

Study burden and risks

In this observational study participants are subject to standard clinical care and follow-up, in which MRI has become standard clinical care in children with perinatal asphyxia and problems at school. In this study, neuropsychological assessment and resting-state sequence will be additional and children who are doing well at school will also be invited to particpate. Risks associated with participation are limited, if not negligible, as MRI has been performed for clinical purposes in almost all follow-up centres for many years. Therefore, considerable collective expertise has been gained in MRI techniques and associated practical issues in teenaged children. Moreover, it has been shown that physical and psychological risks are negligible in this type of MR imaging that does not require administration of sedatives or contrast agents. Performing brain imaging in children this age with this condition is important to understand why children with these conditions have neurocognitive problems, in which the lack of structural abnormalities fails to explain the deficits. In addition, we will be able to see the potential benfit of hypothermia on neuropsychological outcome and networks. Results of the study may aid patients to understand some of the limitations in behaviour or learning they may experience, in turn offering possibilities for intervention. Additionally, this study may contribute to the identification of prognostic parameters for outcome in similar patient populations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

a) 40 full-term infants admitted to a NICU (UMCU or Isala) in the period of 2007-2008 because of acute perinatal asphyxia but without hypothermia
and
b) 40 fullterm infants admitted to a NICU (UMCU or Isala) in the period of 2008-2009 because of acute perinatal asphyxia but treated with hypothermia

Exclusion criteria

- Moderate to severe structural brain damage previously confirmed by MRI;
- Congenital brain abnormalities and/or other (chromosomal/metabolic) anomalies;
- Cerebral palsy;
- Abnormal developmental outcome (DQ<85) at 2 years of age
- Birth weight <10th percentile;
- Contraindications for MRI, such as braces, a pacemaker or claustrophobia.
- Epilepsy (this only applies fo the virtual realty glasses)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-01-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	26-01-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-01-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	22-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-06-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-05-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL44807.041.14