Cerebral injury after neonatal cardiac surgery: Outcome at school age

Published: 03-05-2017
Last updated: 15-04-2024

To gain insight in the cerebral consequences of neonatal cardiac surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45739

Source
ToetsingOnline

Brief title
Cerebral injury after neonatal cardiac surgery: Outcome at school age

Condition

- Congenital cardiac disorders
- Congenital and peripartum neurological conditions
- Cardiac therapeutic procedures

Synonym
congenital heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiac surgery, cerebral, MRI, neonatal

Outcome measures

Primary outcome

The primary endpoint is the prevalence of an abnormal MRI scan in this cohort.

Secondary outcome

* Have the lesions seen at a neonatal age changed, and are there new lesions?

* Is the connectivity different (decreased) in children post-cardiac surgery,

compared to healthy children?

* Do children with lesions on their MRI have less connectivity compared to

those without injury?

* Do more lesions lead to a smaller brain volume?

* Does MRI injury relate to neurodevelopment?

* Does functional connectivity relate to neurodevelopment?

* Is the impact of perinatal asphyxia different to neonatal cardiac surgery, on

the MRI of the brain at school age?

Study description

Background summary

Children born with a complex congenital heart defect, often need life-saving cardiac surgery. As surgical techniques have improved in the past decades, even the most complex defects are still eligible for correction. However, the more complex, and thus longer surgeries, which are performed with the use of cardiopulmonary bypass, entail a higher risk of cerebral injury.

Especially neonates born with an aortic arch obstruction, who undergo surgery which includes cooling to a deep hypothermic temperature (18*C), are at risk of

primarily ischemic brain injury. We observed this in our recently published study in which 37 neonates were imaged using MRI of the brain, and underwent neurodevelopmental testing. Already before surgery, 50% of the neonates had lesions on their cerebral MRI scan, and after surgery 75% of the cohort had new injury. At 2 years of age, 2 of the 23 tested children (9%) had a neurodevelopmental delay.

In the current study, we wish to assess the long-term consequences of complex congenital heart disease. We aim to assess children at an age of 8 years, at which an MRI scan can be expected to be successful without the need for sedation. Also, as MRI techniques have become more sophisticated over the years, one can now assess the connectivity of the brain, using techniques such as diffusion tensor imaging (DTI) and functional MRI (fMRI). This allows us to analyse brain networks, and how these networks are influenced or alteredby cerebral injury.

We hypothesize that children who have evidence of brain injury at school age have different network patterns than healthy children, and that this relates to their neurodevelopmental outcome.

Study objective

To gain insight in the cerebral consequences of neonatal cardiac surgery.

Study design

In this mono-centre, observation al study, children originally included in the randomized controlled trial (RCT), comparing cardiopulmonary bypass techniques during aortic arch reconstruction (protocol number 08-090/K), will be approached for the current study. Therefore, this is a longitudinal study.

We will perform an MRI of the brain, by which MRI injury will be assessed both using conventional MRI sequences, and connectivity techniques (i.e. DTI and fMRI). We will compare the results to those of healthy children, included in the Youth Cohort (Dept. of Psychiatry, METC 11/225), and children after perinatal asfyxia (METC 14/529).

Study burden and risks

In this current observational study, the children will undergo an MRI of the brain, which takes approximately 30 minutes. Sedative medication will not be used, nor will intravenous contrast. Although not compulsory for participation, the child will be offered a practice session in a *mock-MRI*, to reduce anxiety during the scan. Nevertheless, if there is too much anxiety or restlessness during scanning, the scan protocol will be shortened or stopped.

There are no health risks associated with the MRI scan itself. Therefore, considerable collective expertise has been gained in MRI techniques and associated practical issues in children (METC 01/229).

Performing brain imaging in children at this age with this neonatal condition is important to understand why children with these conditions have neurocognitive problems. Results of the study may aid patients to understand some of the limitations in behaviour and/ 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

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584 EA
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
Utrecht 3584 EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Was a participant in the RCT study from 2009-2012
- Has an age of 8 or 9 years.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- If there is a contra-indication for MRI scan (certain types of cardiac devices, braces).
- If the child is unwilling to undergo the MRI scan, due to i.e. claustrophobia.
- In the case of a known genetic syndrome associated with developmental delay.

Study design

Design

Study type:	Observational non 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):	05-10-2017
Enrollment:	34
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-02-2018
Application type:	Amendment
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
ClinicalTrials.gov	NCT01032876
CCMO	NL58777.041.16