Resting state functional MRI in term neonates with perinatal asphyxia

Published: 06-08-2013
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To determine the feasibility of rs-fMRI in neonates undergoing a planned diagnostic MRI session following perinatal asphyxia. To assess intra-session reproducibility (test-retest reliability) of the rs-fMRI technique in neonates with asphyxia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON44127

Source
ToetsingOnline

Brief title
NEOREST

Condition

- Neurological disorders congenital
- Congenital and peripartum neurological conditions
- Neonatal and perinatal conditions

Synonym
asphyxia, cerebral damage

Research involving
Human

Sponsors and support

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

Intervention

Keyword: (rs-)fMRI, asphyxia, brain, newborn

Outcome measures

Primary outcome

1.Feasibility of the rs-fMRI technique will be determined by assessing the image quality of the dynamic scans, the presence of motion artefacts and the temporal SNR.

2. The intra-session reproducibility of the rs-fMRI technique in neonates with asphyxia determined by the mean and Standard Deviation (SD) of the difference between 2 rs-fMRI acquisitions of 6 minutes each of the volume of the activated set of voxels and of the signal intensity of these voxels. Bland-Altman plots and Smallest Detectable Change will be used to report this.

Secondary outcome

nvt

Study description

Background summary

Hypoxic-ischemic encephalopathy (HIE) after perinatal asphyxia in neonates is a serious condition that can cause long-term neurologic sequelae and in severe cases even death. At this moment several clinical diagnostic tests are used to evaluate the severity of the condition: EEG (electroencephalography), cerebral ultrasound and conventional MRI (magnetic resonance imaging) with DWI (diffusion-weighted imaging).
A relatively new possible functional test which needs to be evaluated is resting state functional MRI (rs-fMRI). Rs-fMRI is a relatively new and powerful method which is able to determine differences in patterns in regional brain activity that occur when a subject is not performing an explicit task, i.e. is in a *resting state*. These patterns are closely related to neural subsystems revealed by task-activation fMRI. Because of the lack of task

demands, rs-fMRI is ideally suited for studying these endogenous low-frequency fluctuations in neonates and identifies potential alterations in several important brain networks, such as the visual and sensory/motor module. Although rs-fMRI has proven to be useful in older children, its feasibility in neonates with asphyxia still has to be determined. Also, as in any diagnostic test, the reliability, reproducibility and validity of rs-fMRI has to be proven before it is to be used as a diagnostic and prognostic instrument in clinical practice.

Study objective

To determine the feasibility of rs-fMRI in neonates undergoing a planned diagnostic MRI session following perinatal asphyxia.
To assess intra-session reproducibility (test-retest reliability) of the rs-fMRI technique in neonates with asphyxia.

Study design

A mutlicenter center, cross-sectional study of 30 consecutive enrolled neonates, GA (gestational age) * 36 weeks, diagnosed clinically with perinatal asphyxia.

Study burden and risks

All scans will be performed for clinical diagnosis/ indications. No MR sessions will be performed only for study purposes. The burden for patients is an additional 12 minutes extra scan time in the MRI-scanner. MRI is a non-invasive imaging modality and is considered to be a safe standard medical procedure. The technique has no known complications. The risks associated with study participation involving MRI scanning are negligible. The infants will be safely embedded in blankets and receive hearing protection (earplugs and mini-muffs). In the AMC we use a special MR-incubator (AMC) with monitoring of vital signs. The incubator offers the possibility to investigate possible brain damage in very fragile (even instable or ventilated) neonatal patients in an environment controlled by neonatologists. All clinical data are available digitally for each infant. Regular standard of care treatment will be given for all infants. No experimental treatment will be prescribed. No additional laboratory investigations will be performed. This study poses no risk for any of the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Term neonates clinically diagnosed with perinatal asphyxia.

Exclusion criteria

Lack of informed consent of parents (parental refusal or unable to explain because of language barrier).
Neonate with known congenital malformation(s) of the brain or congenital infection of the brain.
Neonate with known syndrome (e.g. Down syndrome).
Neonate with known congenital neuromuscular disease.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-02-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	06-08-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Not approved

Date:	01-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	31-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	15-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	06-11-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL42456.018.13

Study results

Date completed:	31-05-2016
Actual enrolment:	23