Safety and feasibility of ultra-high field magnetic resonance imaging in neonates

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The primary aim of this study is to investigate the safety and feasibility of ultra-high field magnetic resonance imaging (MRI) of the brain in neonates and to optimize scan protocols.

Ethical review	Approved WMO
Status	Completed
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON49275

Source
ToetsingOnline

Brief title
7.0 Tesla MRI in neonates

Condition

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

Synonym
brain injury, encephalopathy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 7 Tesla, Brain injury, MRI, Neonates, Neurodevelopment

Outcome measures

Primary outcome

The main endpoints of this study are safety, based on the measurement of comfort, feeding intolerance, temperature and vital parameters of the infant, specific absorption rate and sound pressure levels, and the feasibility based on quality of the scan i.e. signal to noise ratio, contrast to noise, B0-inhomogenieties.

Secondary outcome

not applicable

Study description

Background summary

A large part of the infants admitted to the neonatal intensive care unit will experience long-term damage of different organ systems such as the lungs, kidneys and intestines. However, one of the most important consequences on the long term is injury to the developing brain and subsequent poor neurodevelopmental outcome. In our department, all infants who are at risk for brain damage are scanned using MRI to assess brain injury and to predict long term neurodevelopmental outcome. Currently, we use a magnetic field of 3.0Tesla (3.0T), however, for adults the current state of the art is 7.0Tesla (7.0T) MRI, which has shown added value in a growing number of clinical studies. Using 7.0T MRI, it has been shown in adults that micro bleedings and micro-ischemic lesions were better visible, but also the quality of imaging of the white matter tracts, vascularization and magnetic resonance spectroscopy improved. Since it is important for the future of the infant to visualize brain injury early in order to predict outcome and to start early intervention, we expect 7.0T to offer a major improvement in neonatal health care. However, 7.0T MRI has never been performed in infants and a first important step in this research field would be a pilot study to assess safety.

Study objective

The primary aim of this study is to investigate the safety and feasibility of ultra-high field magnetic resonance imaging (MRI) of the brain in neonates and to optimize scan protocols.

Study design

In this observational study, we will investigate the feasibility and safety of 7.0T MRI in 20 infants between the term (equivalent) age (37 weeks gestational age or more) and 3-months post-term. The clinically stable infants will undergo a 7.0T MRI after their routine 3.0T MRI scan on the same to be able to compare both scans. Infants will receive a sedative agent (current standard) before the first (3.0T) MRI according to the clinical protocol. The MRI will be supervised by a neonatologist and a 7.0T imaging expert will be present throughout the second (7.0T) MR examination. Safety will be determined by measuring the infant*s vital parameters, temperature, feeding intolerance and comfort scores before, during and after MRI, as well as the specific absorption rate of the MR scan. Since this is the first time 7.0T MRI will be performed in neonates and to be able to adapt the MRI protocol to the unique properties of the neonatal brain, the 7.0T scan protocols will be developed and optimized whilst scanning the first patients. We will also compare the quality of the scan i.e. signal to noise ratio, contrast to noise, B0-inhomogenieties of the 7.0T compared to the 3.0T MRI.

Study burden and risks

We expect this study to be beneficial to future patients if we find that 7.0T MRI is a safe and feasible technique in neonates. It is expected to offer a more accurate technique to assess the development of the brain on a microstructural level. Furthermore, we think that the extent of (subtle) brain injury can be better visualized, leading to a better prediction of outcome in neonates. This is of importance to provide parents adequate information about the future perspectives of their child, but also allows us in the near future to select the right patients for neuroprotective therapies and to measure the effect of neuroprotective therapies in more detail. Safety and feasibility of 7.0T MRI of the brain in neonates can also provide valuable information for future studies of 7.0T imaging of other organs.
Since the anatomy, water content, damage and development of the brain in neonates are not comparable with adults or older children, this study can only be performed in neonates.
The burden for the infants will be the performance of 2 MRI scans instead of 1 MRI scan. Infants will receive an extra feeding via the nasal tube between the two MRI scans, but will not receive a second dose of chloral hydrate to limit the burden. Possible risks of the 7.0T MRI are an MRI related increase in temperature, peripheral nerve stimulation and discomfort.

We will monitor the infant closely to minimalize the chance of adverse effects and to be able to stop the MRI as soon as there is any evidence of adverse effects or discomfort. Furthermore, there are technical challenges such as an increased risk of artefacts.

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

- Neonates with a clinical indication for MRI in the Wilhelmina Children*s Hospital i.e. stroke, perinatal asphyxia, premature infants between term equivalent age (37 weeks or more) and 3 months post-term;

Exclusion criteria

- Corpus alienum inside or outside the body that cannot be temporarily removed i.e. ferrometal, pacemakers, cochlear implants, hydrocephalus pump, aneurysm clips;
- Instable clinical condition e.g. respiratory support / intravenous or intra-arterial catheters.
- Very irritable or feeding intolerance

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-02-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	07-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	30-06-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-09-2020
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	NL66198.041.18

Study results

Date completed:	24-08-2021
Results posted:	15-03-2022
Actual enrolment:	20

First publication
19-05-2020