Advanced hemodynamic monitoring of the heart and fetal channels in newborn infants using ultrafast ultrasound blood flow imaging

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Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac and vascular disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON46565

Source
ToetsingOnline

Brief title
Ultrafast ultrasound blood flow imaging

Condition

- Cardiac and vascular disorders congenital

Synonym
open ductus, Patent ductus arteriosus

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

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

Intervention

Keyword: Flow, Neonatal, Ultrafast, Ultrasound

Outcome measures

Primary outcome

The main study parameter is the 2D cardiac and transductal blood flow in neonates, visualized by ultrafast ultrasound imaging. The ultrafast data acquisition and flow estimation techniques will be iteratively optimized.

Secondary outcome

Secondary parameters which will be derived from the measurements include cardiac output, maximum velocity through the ductus arteriosus, changes in velocity during heart cycle, vorticity and vector concentration of the velocity field.

Study description

Background summary

There is much controversy about optimal management of patent ductus arteriosus (PDA)
in preterm infants, with the risk of over- and undertreatment. It is hypothesized that with the use of ultrafast ultrasound blood flow imaging it is possible to objectively and accurately quantify 2D flow patterns through this fetal channel. This new technique will provide quantitative measures, which will potentially enable us to generate new parameters to predict spontaneous closure of the PDA.

Study objective

The primary objective of this study is to optimize the ultrafast ultrasound flow imaging technique for intra and extra cardiac flow visualization in neonates. The secondary objectives are 1) to compare cardiac output determined

using conventional Doppler ultrasound versus ultrafast ultrasound imaging and 2) to gain an insight in the 2D flow patterns involved during closure of the PDA.

Study design

This study is a prospective, non-randomized, observational, single-center study. In the study both conventional Doppler ultrasound images and ultrafast ultrasound images will be obtained and compared.

Study burden and risks

For 3 days, once a day two additional ultrasound examinations will be performed: a conventional Doppler ultrasound and an ultrafast ultrasound. The examinations take about 5 minutes each, but will be spread over a time period of about half an hour because of the time it takes to save the ultrafast images. This observational exam is associated with negligible risk according to the risk analysis. Because the study focuses on hemodynamics associated with PDA it is not possible to perform this study in any other patient group than neonates.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Newborn infant admitted to the department of Neonatology
Gestational age of 37 weeks or higher
Informed consent obtained from both parents/guardians

Exclusion criteria

Structural heart defects
Life-threatening congenital defects
Condition which severely affects the skin

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-05-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	05-04-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-07-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL65060.091.18