Onderzoek naar de bloedvoorziening van de hersenen bij kinderen met een aangeboren hartafwijking

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23653

Source
NTR

Brief title
PANCAKE

Health condition

Congenital heart disease, ductus arteriosus, near-infrared spectroscopy, Doppler flow profiles, general movements, Prechtl's method, neurological outcome, neonate

Congenitale hartafwijkingen, ductus arteriosus, near-infrared spectroscopy, Doppler flow profielen, general movements, Prechtl's methode, neurologische ontwikkeling, neonaat

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

General movements (GMs) according to Prechtl's method

Secondary outcome

Multisite near-infrared spectroscopy (NIRS)
Antenatal doppler flow profiles

Study description

Background summary

Infants with congenital heart disease are at risk of developing brain damage. This study is designed to gain more insight into the timing of brain damage via non-invasive clinical tools such as antenatal Doppler flow profiles, multisite near-infrared spectroscopy and general movements according to Prechtl's method.

Study objective

The objective of the study is to gain more insight into brain damage in infants with congenital heart disease. We hypothesize that infants with congenital heart disease are at risk of developing brain damage during early life or even before birth.

Study design

From diagnosis before birth to an age of three months.

GMs: age of seven days and age of three months

NIRS: day 1-7 after birth, during and after corrective surgery

Antenatal Doppler flow profiles: every 4 weeks after diagnosis

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

A cardiac anomaly on ultrasound before birth
Admission to the NICU after birth

Exclusion criteria

Premature birth before a gestational age of 36 weeks

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-04-2014
Enrollment:	25
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-05-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40142
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5101
NTR-old	NTR5233
CCMO	NL45567.042.14
OMON	NL-OMON40142

Study results