Non-invasive measurements of hemodynamic transition at birth

Published: 05-09-2011
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To explore the hemodynamic changes during transition at birth by gathering non-invasive physiological data in healthy term infants.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON37751

Source
ToetsingOnline

Brief title
(HART) Hemodynamic measurements At biRTh

Condition

- Other condition

Synonym
hemodynamic changes at birth

Health condition

hemodynamiek bij geboorte

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Fysiological transition, Hemodynamic measurements, Newborn infant

Outcome measures

Primary outcome

1) Oxygenation and heart rate

2) Perfusion index

3) Contraction force of the heart

4) Non invasive blood pressure

5) Changes in regional oxygen saturation of the brain (rSO2brain) measured with

near-infrared spectroscopy (NIRS)

6) Changes in blood flow through the ductus arteriosus

Secondary outcome

none

Study description

Background summary

The transition to extra uterine life at birth is one of the greatest physiologic challenges that most humans encounter. It begins with lung aeration and the onset of air-breathing. Liquid that fills the airways must be cleared immediately after birth to allow entry of air, recruitment of a functional residual capacity (FRC) and onset of pulmonary gas exchange. These processes initiate respiratory and cardiovascular responses in the newborn including a large increase in pulmonary blood flow, closure of vascular shunts, the onset of sustained regular breathing, and increased blood oxygenation.

Recent research has been focusing on the factors that regulate lung aeration and the establishment of FRC at birth. Hemodynamic changes that need to take place after birth are also essential for adequate gas exchange and oxygenation of the vital organs. These are regulated by a complex, interactive group of factors, which interplay is incompletely understood. Much of our knowledge at

birth is based on animal studies. Data on human fetuses and newborns are sparse because of the invasive techniques that would be necessary to obtain them.

Traditionally the only objective parameter measured for evaluation of the hemodynamic condition of the infant at birth is heart rate. Oxygen delivery to the peripheral tissue is defined by the peripheral blood flow and arterial oxygen content. More information is needed to evaluate the hemodynamic condition at birth because peripheral blood flow is dependent on cardiac output and peripheral vascular resistance. There is very little human data available on hemodynamic changes during transition directly after birth. A better understanding is essential when attempting to understand problems associated with circulation in the immediate newborn period and develop strategies to support transition.

Study objective

To explore the hemodynamic changes during transition at birth by gathering non-invasive physiological data in healthy term infants.

Study design

Prospective observational study performed in the Leiden University Medical Center (LUMC)

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy term (>36 weeks of gestation) infants delivered by caesarian section.

Exclusion criteria

All children with a congenital malformation, in need of respiratory support or those who are given additional inspired oxygen.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	08-11-2012
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL37720.058.11