The effect of breathing on placental venous return in infants at birth: an observational study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON46740

Source
ToetsingOnline

Brief title
BABy study

Condition

- Neonatal and perinatal conditions
- Neonatal respiratory disorders

Synonym
bloodflow from placenta to the newborn, placental transfusion

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Vidi beurs

Intervention

Keyword: Bloodflow, Delayed Cord Clamping, Placental transfusion, Spontaneous breathing

Outcome measures

Primary outcome

Bloodflow patterns in the umbilical vein, ductus venosus, vena cava inferior

and hepatic vein and the effect of breathing on bloodflow patterns in these

vessels.

Secondary outcome

N.A.

Study description

Background summary

Several studies have demonstrated a beneficial effect of delayed cord clamping (DCC) in infants at birth and DCC is increasingly implemented in clinical practice. These beneficial effects have been attributed to the increase of neonatal blood volume from the placenta (placental transfusion) that occurs during the period that the cord remains intact after birth. Although the placental-to-infant transfusion has been described, the underlying physiological mechanism that is responsible for this transfusion remains unclear.

Study objective

In this research study we observe the effect of breathing on placenta- to infant transfusion, by measuring bloodflow in the umbilical vein, vena cava inferior, ductus venosus and hepathic vein, to get a better understanding of the underlying mechanisms and fysiology of placental transfusion. If breathing has an effect on placenta-to infant transfusion this could lead to a better understanding of the optimal time of cord clamping. This optimal time of cord clamping might be after adequeate breathing has commenced.
The objective of this study is to observe the effect of breathing on the placenta- to infant transfusion, directly after birth

Study design

Prospective, observational study

Study burden and risks

There are no know risks associated with ultrasonographic Doppler measurements or the use of echocardiography measurements.
A possible risk could be the chance of interference between mother-child bonding whilst obtaining ultrasonography measurements. Although this has not been studied, we recently performed a similar study where the ultrasonography did not interfere with the first bonding. Conform standard the infants will be placed immediately on the mother*s chest. Also, we will only approach multigravida mothers, to minimize the risk of interference.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Healthy infants born in Leiden Univeristy Medical Centre birth centre
Gestational age at least 37 weeks, of multiparous mothers
No need for resuscitation/respiratory support at birth

Exclusion criteria

Refusal of antenatal informed consent
Known major anomalies
Need for resuscitation/respiratory support at birth

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-02-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	25-08-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	05-02-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-03-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL62132.058.17

Study results

Date completed:	22-06-2020
Actual enrolment:	15

Summary results
Trial ended prematurely