Assessing blood flow chracteristics across the foramen ovale in term infants during transition at birth: an observational study.

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The aims of this study are [1]. to investigate the flow hemodynamics through the foramen ovale (FO) directly after birth and [2]. to assess how these changes are influenced by breathing and the timing of umbilical cord clamping in healthy term...

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

Summary

ID

NL-OMON57008

Source
ToetsingOnline

Brief title
SHUNT study.

Condition

- Other condition

Synonym
nvt.

Health condition

Geen.

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Het onderzoek wordt met 10.000 euro ondersteund door het Strong Babies fonds;dit wordt gebruikt voor de kosten van de monitor;de uiteindelijke publicatiekosten en het overige geld wordt gebruikt voor het salaris van de arts-onderzoeker. Hiernaast is er geen andere geldstroom specifiek voor dit onderzoek. Het salaris van de onderzoeker is bepaalt volgende de CAO Universitair Medisch Centra (https://www.nfu.nl/voor-umc-medewerkers/cao-universitair-medische-centra) op schaal 1 (0.8 FTE) en gefinancierd vanuit onderzoeksproject van prof. dr. A. te Pas (neonatoloog LUMC)

Intervention

Keyword: Fetal cardiac shunt, Foramen ovale, Physiological based cord clamping, Spontaneous breathing, Transition

Outcome measures

Primary outcome

• Ultrasonographic doppler velocimetry measurements of blood flow through the FO and DA (to confirm the short circuit circulation) will be measured and recorded immediately after birth while the infant remains attached to the umbilical cord. Moreover, measurements will be done after umbilical cord clamping.

Secondary outcome

• Diaphragm movements will be recorded simultaneously using ultrasonography to correlate respiratory activity with cardiovascular changes. This will help elucidate the impact of breathing on FO flow hemodynamics.

• Lastly, electrocardiography (ECG) monitoring will be employed throughout the study to provide a comprehensive assessment of heart rate variability and its relationship to FO flow changes during the cardiac cycle (i.e. systolic and

diastolic phase).

Study description

Background summary

Directly after birth, major cardiovascular changes occur during transition from intra-uterine to extra-uterine life. Normally, the cardiovascular adaptation during transition to life occurs uneventful without any hemodynamic compromise. The pulmonary and circulatory transition are intimately linked and lung aeration is the master switch for increase in pulmonary blood flow. Recent data has shown that the direction of flow over fetal shunts (ductus arteriosus (DA), ductus venosus, foramen ovale) play a vital role during these crucial changes.1 During the increase in pulmonary blood flow concomitantly a reversal of ductal shunt occurs, leading to a short circuit circulation (pulmonary artery-left heart-aorta-pulmonary artery). Research has shown in healthy term newborns flow changes over the DA from predominantly right-to-left shunting to predominantly left-to-right shunting at 10 minutes after birth, contributing to this short circuit.2 It is speculated that this temporarily short circuit provides acclimating time for the heart to get adapted to the hemodynamic changes. This short circuit most likely will lead to a more predominant left to right shunt over the FO. However, there is very little data on the behavior of the shunt over the FO and how this relates to cord clamping. In addition, recent data demonstrated that blood flow over the ductus venosus increases during inspiration.3 While it is generally believed that this could potentially result in an elevation of right ventricular preload, its occurrence would hinge on the direction of the shunt through the FO and its role in augmenting pulmonary circulation. Consequently, gaining insight into the flow of blood through the FO during the transitional phase would enable us to define the most favorable moment for umbilical cord clamping from a hemodynamic perspective. Understanding the cardio-physiological changes that occur during transition from intrauterine to extrauterine life and adverse adaptation are crucial for healthcare providers caring for neonates. Therefore we aim to investigate blood flow patterns through the FO in healthy full-term infants directly after birth and determine how this is influenced by breathing and cord clamping.

Study objective

The aims of this study are [1]. to investigate the flow hemodynamics through the foramen ovale (FO) directly after birth and [2]. to assess how these changes are influenced by breathing and the timing of umbilical cord clamping in healthy term infants.

Primary Objective: To assess the cardiovascular changes and blood flow

hemodynamics through the FO in term infants immediately after birth, utilizing transthoracic ultrasound.

Secondary Objective(s): To evaluate the effect of breathing and the timing of umbilical cord clamping on the flow hemodynamics across the FO during the critical transition from fetal to neonatal circulation.

Study design

We will perform a single center prospective observational study in healthy full-term infants at the Department of Obstetrics and Neonatology of the Leiden University Medical Center (LUMC). The observational nature of the study allows us to capture real-time data without interventions that might affect the physiological processes directly after birth.

Study burden and risks

There are no benefits to this study. A possible risk could be the chance of interference between mother-child bonding whilst obtaining ultrasonography measurements. Although this has not been previously studied, we recently performed similar studies where the ultrasonography did not interfere with the first bonding.2,3 It was not necessary to stop the procedure in any of the occasions and the feedback of the parents was positive. Conform standard, the infants will be placed immediately on the mother*s chest. Also, we will only approach multigravida mothers. Group relatedness of this study is based on the measurement taken whilst the child is still attached to the umbilical cord and measurements directly after umbilical cord clamping.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns

Inclusion criteria

Only healthy term infants (37-42 weeks of gestation) of singleton multiparous low-risk pregnancies, delivered by spontaneous vaginal delivery, are eligible for measurements within the first minutes after birth.

Exclusion criteria

Exclusion criteria are determined based on the acknowledgment of the stressful nature of childbirth, particularly for primigravida mothers. Therefore, we exclusively approach multiparous mothers, excluding those giving birth to their first child. Additionally, patients with a gestational age of less than 37 weeks, high-risk pregnancies (including infants with known or suspected anatomic malformations such as congenital heart disease (CHD) or pulmonary diseases), and infants requiring respiratory support or supplemental oxygen during the transition are excluded. This study solely includes infants who experience an uncomplicated transitional period.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO Date:	09-09-2024
Application type:	First submission
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	NL85883.058.23