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Effect of timing of cord clamping in newborns during first 10 minutes of birth

Submission date
29/03/2016

Recruitment status
No longer recruiting

Registration date
05/04/2016

Overall study status
Completed

Last Edited
05/06/2019

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A baby's heart rate is one of the most important indicators of good health at the time of birth. It can be used to assess whether a baby requires additional support for breathing, as a low heart rate (less than 100 beats per minute) is used as a sign to start ventilation (helping a baby to breathe using a breathing machine). At the time of birth, the infant is still attached to the placenta via the umbilical cord. The infant is usually separated from the placenta by clamping the cord with two clamps, and cutting between the clamps. It is thought that a low heart rate at birth can be caused by a lower amount of blood circulating around the baby's body due to early umbilical cord clamping (when the umbilical cord is clamped 60 seconds or less after birth). By delaying cord clamping, it is possible that more blood is able to return to the baby's heart which initiates a healthy heart rate of over 100 beats per minute (bpm). The aim of this study is to find out whether delaying clamping of the umbilical cord for more than 180 seconds can help to increase the newborn baby's heart rate to more than 100 bpm.

Who can participate?
Healthy women who are about to give birth to a single baby.

What does the study involve?
Participants are randomly allocated to one of two groups. For all women, a special heart rate monitor is placed on their stomach just before giving birth to monitor their baby's heart rate. After they have given birth, the baby is then place on their stomach until the umbilical cord is clamped and another heart rate monitor is placed on the baby's chest for 10 minutes to continuously monitor the heart rate. The time until the baby starts breathing is also recorded in seconds. For participants in the first group, the umbilical cord is clamped 60 seconds after they have given birth. For participants in the second group, the umbilical cord is clamped 180 seconds after giving birth. The heart rates of the babies in each group and the time until they start breathing is then compared between the two groups.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with taking part in the study.

Where is the study run from?
Paropakar Maternity and Women's Hospital (Nepal)

When is the study starting and how long is it expected to run for?
April 2016 to October 2016

Who is funding the study?
UNICEF (USA)

Who is the main contact?
1. Dr Ashish Kc (scientific)
2. Professor Nalini Singhal (scientific)
3. Dr Ola Andersson (scientific)

Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of timing of cord clamping in the healthy late preterm and term neonate on heart rate during first 10 minutes of birth: A randomized controlled study in a hospital of Nepal

Study objectives
Delaying the clamping of cord for more than 180 seconds will have more venous blood return to the heart and increase the heart rate to more than 100 bpm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nepal Health Research Council, 21/01/2016, ref: 92/2015

Study design
Single-centre randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Neonatal heart rate

Interventions
Participants will be randomly assigned to one of two parallel groups in a 1:1 ratio a few minutes before delivery using envelope randomisation.

For all women, once they go into labour they are transferred to the Maternal and Newborn Service Center and the surveillance officer at the MNSC will place a Moyo's Fetal Heart Rate Monitor in the mother's abdomen to continuously monitor the fetal heart rate. A surveillance officer will be dedicated to each women to monitor the fetal heart rate and ensure attachment of the Moyo's FHR monitor. Another surveillance officer, will be present at the time of delivery of infant's shoulder to cord clamping using a stopwatch. Immediately after the delivery of the baby, the Moyo's FHR monitor will be placed by another SO in the baby's precordium to monitor the heart rate of the baby until 10 minutes of birth as well as time of first cry or breathe of the baby. The nurse-midwife will place the baby on the mother's abdomen as routine procedure until the cord was clamped.

Group 1: In the early-clamping group, the SO will inform the nurse-midwife when 60 seconds was approaching and informed that cord should be clamped if not done earlier.
Group 2: In the delayed-clamping group, the SO will inform the nurse-midwife when 180 seconds had passed and the cord should be clamped.

Intervention Type
Procedure/Surgery

Primary outcome measure
Neonatal Heart rate measured using a Moyo's Fetal Heart Rate Monitor at continuously from the time of birth until 10 minutes of birth and 1, 3 and 5 minute.

Secondary outcome measures
1. Baby's condition is measured using Apgar score at 1, 5 and 10 minutes
2. Time of establishment of spontaneous breathing is measured in seconds from the time of birth until 10 minutes
3. Neonatal Heart rate measured using a 1, 3, 5 and 10 minutes
4. Neonatal Heart rate measured using Massimo pulse oximeter continuously from the time of birth until 10 minutes of birth
5. Neonatal blood oxygen saturation measured using a Massimo pulse oximeter at 1, 3, 5 and 10 minutes
6. Neonatal blood oxygen saturation measured using a Massimo pulse oximeter continuously from the time of birth until 10 minutes of birth
7. Neonatal pulsatility index measured using a Massimo pulse oximeter at 1, 3, 5 and 10 minutes
8. Neonatal pulsatility index measured using a Massimo pulse oximeter continuously from the time of birth until 10 minutes of birth.
9. Body temperature (10-30 minutes after birth)
10. Respiratory distress at one hour after birth
11. Transcutaneous bilirubin at discharge
12. Baby's condition at discharge (live/neonatal death)

Overall study start date
10/04/2016

Completion date
15/10/2016

Eligibility

Key inclusion criteria
1. Women in active labour coming for delivery in the Maternal Newborn Service Center (MNSC)
2. Normal vaginal delivery
3. Women with no complication during delivery
4. Fetal Heart Rate (FHR≥100≤160bpm)
5. Women with gestational age (≥33 weeks)

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
755 participants in each group

Total final enrolment
1500

Key exclusion criteria
1. Antepartum Stillbirth
2. Intrapartum stillbirth
3. Congenital anomaly
4. Multiple gestation
5. Neonate not breathing at birth

Date of first enrolment
15/04/2016

Date of final enrolment
30/07/2016

Locations

Countries of recruitment
Nepal

Study participating centre
Paropakar Maternity and Women's Hospital
Thapathali
Kathmandu
Nepal
P.O Box 1187

Sponsor information

Organisation
Uppsala University Hospital

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Sponsor type
University/education

Website
www.kbh.uu.se/imch

ROR
https://ror.org/01apvbh93

Funder(s)

Funder type
Charity

Funder Name
UNICEF

Alternative Name(s)
United Nations Children's Fund, United Nations Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
United States of America

Funder Name
Swedish Research Council

Funder Name
Swedisih Society of Medical Research (Svenska Sällskapet för Medicinsk Forskning)

Alternative Name(s)
Swedish Society for Medical Research, SSMF

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location

Sweden

Results and Publications

Publication and dissemination plan

1. Planned publication of a study protocol and results paper in peer reviewed journals
2. Planned dissemination of the results in international neonatology conference in 2017

Intention to publish date

15/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/05/2019	05/06/2019	Yes	No