

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

Submission date 29/03/2016	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 05/04/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/06/2019	Condition category Circulatory System	☐ 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 placed 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

Type(s)
Scientific

Contact name
Dr Ashish Kc

ORCID ID
<https://orcid.org/0000-0002-0541-4486>

Contact details
UNICEF
UN House
Pulchowk
Lalitpur
Nepal
P.O Box 1187

Type(s)
Scientific

Contact name
Prof Nalini Singhal

Contact details
Department of Pediatrics
University of Calgary
Calgary, Alberta
Canada
+403

Type(s)
Scientific

Contact name

Dr Mats Målqvist

Contact details

Department of Women's and Children's Health
International Maternal and Child Health
Uppsala University Hospital
Drottninggatan 4
Uppsala
Sweden
+46

Type(s)

Scientific

Contact name

Dr Ola Andersson

ORCID ID

<https://orcid.org/0000-0002-3972-0457>

Contact details

Department of Women's and Children's Health
International Maternal and Child Health
Uppsala University Hospital
Drottninggatan 4
Uppsala
Sweden
+46

Additional identifiers

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

Primary study design

Interventional

Study design

Single-centre randomised parallel trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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)

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 $\geq$ 100 $\leq$ 160bpm)
5. Women with gestational age ($\geq$ 33 weeks)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

Female

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

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, United Nations International 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

Swedish 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

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