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# Can squeezing blood from the umbilical cord into the baby reduce death and illness in premature babies?

**Submission date**
10/11/2018

**Recruitment status**
No longer recruiting

**Registration date**
15/11/2018

**Overall study status**
Completed

**Last Edited**
29/09/2021

**Condition category**
Pregnancy and Childbirth

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

## Plain English summary of protocol

This study is held in a single centre. The baby who was born less than 30 weeks of gestational age will be eligible to the study. After getting the informed consent from the parents. The baby will be randomly assigned to two groups, the milking group and the clamping group. After the baby birth, obstetricians cut the umbilical cord leaving at least 20cm. For the milking group – the baby was placed under the radiant warmer and the umbilical cord raised and milked from the cut end towards the baby with a speed of 10 cm/ sec, and clamped at 2–3 cm by the end of initial steps. The milking was done by the neonatologist while re- suscitation was done by the accompanying paediatrician certified in NRP and nurse attending the delivery. For the control arm - the umbilical cord of 20 cm was clamped near the umbilicus and cut without doing cord milking.
All of the patient data including maternal hemoglobins, maternal age, maternal health issue during pregnancy, complication during delivery, delivery mode, hemoglobins, hematocrit, peak bilirubin level, mean arterial pressure of the baby will be collected. The clinical outcome of the baby, including death, bronchopulmonary dysplasia, intraventricular hemorrhage, necrotizing enterocolitis and retinopathy of prematurity will also be collected. These data will be analyzed statistically.

Background and study aims
The survival rate of extremely premature babies is increasing because of improvements in care in the past 20 years. However, treatment for these premature babies in the first few days of life is still very challenging. The babies may have multiple problems involving their lungs, heart and circulation, digestive system and brain. respiratory system, cardiovascular system, gastrointestinal system, central nervous system. Researchers have suggested that premature babies might benefit from placental transfusion strategies, which aim to get as much blood and nutrients from the placenta and umbilical cord as possible into the baby before the cord is cut. This study aims to investigate umbilical cord milking, in which a doctor squeezes the umbilical cord to push the blood towards the newborn before the cord is clamped and cut.

Who can participate?
Premature babies born at less than 30 weeks of pregnancy.

What does the study involve?
The participants will be randomly allocated into one of two groups - the cord milking group and the cord clamping group. The participants in the cord milking group will receive umbilical cord squeezing at birth as well as usual care. Meanwhile, the participants in cord clamping group will receive usual care only. The study will investigate the initial blood tests and medical records of all participants to see whether there is any difference between two groups in terms of survival or illness.

What are the possible benefits and risks of participating?
The potential benefit in the cord milking group is that the baby might have more blood after birth and might not need heart-stimulating drugs. The potential risk in the cord milking group is that jaundice (yellowing) requiring phototherapy (light treatment) may be slightly higher than in the cord clamping group. This is because a newborn baby's liver is often not working fully to break down bilirubin, a substance produced when old red blood cells are broken down. The investigator and healthcare professionals who take care of the babies will closely monitor their clinical condition of participants and treat them as necessary.

Where is the study run from?
MacKay Children’s Hospital, Taipei, Taiwan

When is the study starting and how long is it expected to run for?
June 2015 to December 2018

Who is funding the study?
There are minimal additional costs because the babies are receiving usual care and the cord milking process has no cost.

Who is the main contact?
Dr Shang-po Shen
littlepo0327@gmail.com

# Contact information

### Type(s)
Public

### Contact name
Mr Shang Po Shen

### Contact details
No.92, Sec. 2, Zhongshan N. Rd., Zhongshan Dist.
Taipei City
Taiwan
104

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
UCM2015001

# Study information

### Scientific Title
Impact of one-time umbilical cord milking after cord cutting on morbidity and mortality of extremely preterm infants

### Study objectives
Umbilical cord milking after the cord cutting improves outcomes for extremely preterm infants.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
MacKay Memorial Hospital Institutional Review Board, 26/12/2015, 14MMHIS264

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

### Health condition(s) or problem(s) studied
Preterm baby (less than 30 weeks of gestational age)

### Interventions
This study is held in a single centre. After informed consent has been provided the parents, the baby will be randomly assigned to one of two groups, the milking group and the clamping group. After the birth, an obstetrician will cut the umbilical cord leaving at least 20 cm. For the cord milking group, the baby will be placed under the radiant warmer and the umbilical cord raised and milked from the cut end towards the baby with a speed of 10 cm/s and clamped at 2–3 cm. The milking will be performed by a neonatologist while resuscitation will be conducted by an accompanying paediatrician certified in the Neonatal Resuscitation Program (NRP) and the nurse

attending the delivery. For the control arm, the umbilical cord was initially cut to 20 cm and then was clamped near the umbilicus and cut without cord milking.

### Intervention Type
Procedure/Surgery

### Primary outcome measure
1. Neonate's hemoglobin level at admission
2. Neonate's hematocrit at admission
3. Neonate's mean arterial pressure at admission
4. Administration of inotropic agents in first 72 h post-birth
All data will be taken from medical records.

### Secondary outcome measures
1. Rate of death before post-menstrual age (PMA) of 36 weeks assessed by reviewing the patient’s medical records
2. Rate of bronchopulmonary dysplasia assessed by reviewing the patient’s medical records
3. Rate of all-stage intraventricular hemorrhage assessed by reviewing the patient’s medical records
4. Rate of severe intraventricular hemorrhage assessed by reviewing the patient’s medical records
5. Rate of necrotizing enterocolitis assessed by reviewing the patient’s medical records
6. Rate of retinopathy of prematurity assessed by reviewing the patient’s medical records
Neonates will be followed up from birth until first discharge from hospital.

### Overall study start date
01/06/2015

### Completion date
25/03/2019

## Eligibility

### Key inclusion criteria
Preterm (born at less than 30 weeks of gestational age)

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Both

### Target number of participants
100

### Total final enrolment
78

### Key exclusion criteria
1. Known congenital anomaly
2. Fetal anemia
3. Hydrops fetalis
4. Unknown specific gestational age
5. Umbilical cord is less than 20 cm long
6. Received resuscitation after birth and receiving one or more doses of epinephrine

### Date of first enrolment
26/12/2015

### Date of final enrolment
25/12/2018

## Locations

### Countries of recruitment
Taiwan

### Study participating centre
**MacKay Children's Hospital**
No.92, Sec. 2, Zhongshan N. Rd., Zhongshan Dist.
Taipei City
Taiwan
104

## Sponsor information

### Organisation
MacKay Children's Hospital

### Sponsor details
No.92, Sec. 2, Zhongshan N. Rd., Zhongshan Dist.
Taipei City
Taiwan
104
+886225433535
mmhsuper@mmh.org.tw

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/015b6az38

# Funder(s)

**Funder type**
Other

**Funder Name**
Self-funded

# Results and Publications

**Publication and dissemination plan**
Results will be published in a journal.

**Intention to publish date**
25/12/2019

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are not expected to be made available due to the restrictions of the Institution Review Board (IRB).

**IPD sharing plan summary**
Not expected to be made available

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 28/09/2021 | 29/09/2021 | Yes | No |