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Efficacy and safety of delayed cord clamping versus umbilical cord milking in term neonates

Submission date
21/08/2016

Recruitment status
No longer recruiting

Registration date
29/08/2016

Overall study status
Completed

Last Edited
15/01/2021

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
After birth, blood flow in the umbilical cord usually continues for a few minutes. Additional blood is transferred from the mother to the baby during this time, known as placental transfusion. The ideal time to clamp the cord has been an active research area in the last decade. Delayed cord clamping (DCC) and umbilical cord milking (UCM) allow excess residual cord blood to be transferred to the baby rather than going to waste. Both techniques of handling the umbilical cord at birth have been shown to be feasible, effective and safe. Both UCM and DCC reduce the risk of anemia compared to immediate cord clamping. Iron deficiency anemia, where a lack of iron in the body leads to a reduction in the number of red blood cells, is a common health problem among children, especially in developing countries. The aim of this study is to assess the effectiveness and safety of delayed cord clamping versus umbilical cord milking in full-term babies.

Who can participate?
Mothers giving birth at full term (gestational age over 37 weeks)

What does the study involve?
Mother-infant pairs are randomly allocated to either the UCM or the DCC group. Infants in the UCM group are placed at or below the level of the placenta if delivered vaginally or at the same level as the placenta if delivered by cesarean section, and 20cm of the umbilical cord is actively milked towards the navel three times before clamping the cord. For infants in the DCC group, the umbilical cord is clamped after 60 seconds. All mothers and infants are followed up when the infant is between 8 and 12 weeks of age.

What are the possible benefits and risks of participating?
There won't be any financial reward for participating in the study. Moreover, there are no anticipated harms from participating in this study based on previous research.

Where is the study run from?
King Abdulaziz University Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
March 2015 to December 2016

Who is funding the study?
King Abdulaziz University Hospital (Saudi Arabia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
79-15

Study information

Scientific Title
The efficacy and safety of delayed cord clamping versus umbilical cord milking in term neonates: a randomized clinical trial

Study objectives
There is no difference between umbilical cord milking (UCM) and delayed cord clamping (DCC) in ferritin level in infants between 8-12 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)

King Abdulaziz University Research Ethics Committee, 25/03/2015, ref: 79-15

Primary study design
Interventional

Study design
Single-centre unblinded parallel-arm randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Infantile-onset iron deficiency anemia

Interventions
No previous studies are available which have compared these two interventions in term infants. In order to detect a 30% difference in mean ferritin levels between the delayed cord clamping and umbilical cord milking groups at 3 months of age with a power of 80% and a significance level of 0.05, a total sample size of about 120 infants will be required for the study. Assuming that 20% are lost to follow up, we will recruit a total of 150 infants.

Mother-infant pairs will be randomly allocated to either umbilical cord milking or delayed cord-clamping group. Allocation will be performed using a computer-generated list prepared by an independent biostatistician. The random numbers will be generated in 1:1 allocation, without stratification. The list will be kept confidential to primary investigators. The allocation codes will be placed in sequentially numbered opaque and sealed envelopes. The envelopes will be kept in or delivery room in a lock and key cabinet and will be the responsibility of the in-charge nurse at delivery room.

Infants in the cord milking group will be placed at or below the level of the placenta if delivered vaginally or at the same level as the placenta if delivered by cesarean section, and 20cm of the umbilical cord will be actively milked towards the umbilicus three times before clamping the cord.

For those randomized to the delayed cord milking, the umbilical cord will be clamped at 60 seconds. A stopwatch in every delivery room will be used to measure the 60 seconds of delayed cord clamping.

Follow up will be between 8 and 12 weeks of age . Some of the infants will have their blood drawn at 2 months of age but if they missed the vaccination time (2 months) we allowed them to come back up to 12 weeks (3 months) of age.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Serum ferritin (ng/ml) at 8-12 weeks of age

Key secondary outcome(s)
1. Neonatal outcomes:
1.1. Management in delivery room (right after delivery):

1.1.1. Cord arterial and venous pH
1.1.2. Apgar score at 1 and 5 minutes
1.1.3. Need for resuscitation beyond suction and gentle simulation
1.2. Hematological values:
1.2.1. Venous Hgb value at 24 h (g/dl)
1.2.2. Venous Hct value at 24 h (%)
1.2.3. Bilirubin level at 24 h (umol/L)
1.2.4. The need for phototherapy during nursery stay
1.2.5. Maximum bilirubin level during nursery stay
1.2.6. Polycythemia defined as venous Hct > 65% during nursery stay
1.2.7. Hgb (g/dl) values at 8-12 weeks of life
1.3. Short-term outcomes (before discharge from hospital)
1.3.1. Admission to NICU
1.3.2. Respiratory distress syndrome

2. Maternal outcomes (before discharge from hospital):
2.1. Mortality
2.2. Estimated blood loss
2.3. Post-partum Hgb at 24 h
2.4. Need for blood transfusion
2.5. Need for manual removal of retained placenta
2.6. Length of the 3rd stage

Completion date
30/12/2017

Eligibility

Key inclusion criteria
Anticipated full-term birth at GA > 37 weeks confirmed by US in first trimester or last menstrual period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
149

Key exclusion criteria
1. Multiple pregnancy
2. Placenta Previa and abruption

3. Major congenital or chromosomal abnormality
4. Cord prolapse
5. Ruptured vasa previa
6. Rh sensitization
7. Fetal hydrops
8. Significant vaginal bleeding as assessed by obstetrician 24 h prior to delivery.
9. True umbilical cord knot
10. Suspected perinatal asphyxia
11. Suspected meconium aspiration
12. Fetal anomaly that required immediate resuscitation (diaphragmatic hernia)
13. Maternal infection (human immunodeficiency virus, hepatitis A, B or C)
14. Delivery in emergency room

Date of first enrolment
01/04/2015

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Abdulaziz University Hospital
Saudi Arabia
21589

Sponsor information

Organisation
King Abdulaziz University

ROR
https://ror.org/02ma4wv74

Funder(s)

Funder type
University/education

Funder Name
King Abdulaziz University of Saudi Arabia

Alternative Name(s)
, L'université du Roi Abdulaziz, La Universidad Rey Abdulaziz, King Abdulaziz University of Saudi Arabia, KAU

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Saudi Arabia

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	25/08/2020	15/01/2021	Yes	No