Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation and comparison of neonatal complications of two methods of umbilical cord milking and early cord clamping in neonates

Protocol summary

Study aim

Determination and comparison of neonatal complications of two methods of umbilical cord milking and early cord clamping in preterm infants from 28 to 34 weeks.

Design

Clinical trial includes control group, with parallel groups, without blinding and randomization, performed on 160 preterm infants

Settings and conduct

In developing countries, due to low available blood resources and the possibility of transmission of blood-borne infections, decrease in the need for transfusion is a valuable achievement. This is a randomized clinical trial study which will be applied to preterm infants born in Imam Reza and Ghaem Hospitals. Naturally delivered preterm infants or those born with cesarean section who qualify based on inclusion criteria of study are randomly assigned to two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All infants who are not suspected of placental abruption and in sonography, for a gestational age of 28 to 34 weeks, there should be no sign of placenta previa, anemia, hydrops and embryonic major abnormalities. Exclusion criteria: In a case that the infant is not hospitalized in NICU or during the study, parents do not agree with the presence of their infant in the study, less than 25 cm length of umbilical cord, thick meconium, the true knot of the umbilical cord, major anomalies of umbilical cord

Intervention groups

In control group, early cord clamping method and in the intervention group, the umbilical cord milking method are applied to preterm infants of 28 to 34 weeks.

Main outcome variables

The amount of transfused blood, the amount of bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038586N1**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Atena Sadat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2806

Email address

sadata931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison of neonatal complications of two methods of umbilical cord milking and early cord clamping in neonates

Public title
Investigation and comparison of neonatal complications of two methods of umbilical cord milking and early cord clamping in neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The infant's parents should give written informed consent for the infant to enter the study All infants who are not suspected of placental abruption For a gestational age of 28 to 34 weeks, in sonography, there should be no sign of placenta previa, anemia, hydrops and embryonic major abnormalities.
Exclusion criteria:
Less than 25 cm length of umbilical cord Thick meconium The true knot of the umbilical cord Major anomalies of umbilical cord In a case that the infant is not hospitalized in NICU or during the study, the parents do not agree with the presence of their infant in the study
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation table for patients will be generated by a computer. The numbered envelopes are then provided and the intervention or control group is placed in a sealed envelope according to the random allocation table.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
345 - 91357
Approval date
2017-10-18, 1396/07/26
Ethics committee reference number
IR.MUMS.REC.1396.171

Health conditions studied

1

Description of health condition studied
preterm infants
ICD-10 code
P07.3
ICD-10 code description
Preterm [premature] newborn [other]

Primary outcomes

1

Description
The amount of transfused blood
Timepoint
The amount of transfused blood in the first 120 hours
Method of measurement
Blood sampling

2

Description
The amount of bilirubin
Timepoint
The amount of bilirubin is measured daily
Method of measurement
Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Control group: shortly after the birth, early cord clamping is performed
Category
Treatment - Devices

2

Description
Intervention group: After the birth, the umbilical cord milking method is applied. The milking method is that after the birth, the infant while being at or slightly below

the mother's body level, a piece of 25 cm of the cord remains tangential to the body of the fetus. Then, this piece is milked by the midwife who places the infant under the warmer, 3 times, each of which takes 2 to 3 seconds. The milking is performed from the placenta of the umbilical cord to the embryo (total of 10 seconds). In this situation, about 20 cc of blood is injected into the infats's body.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Sara Mirzaeian

Street address
Ahmad Abad Ave, Ghaem hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699199

Phone
+98 51 3801 2477

Email
mirzaeians@mums.ac.ir

2

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
Atena Sadat

Street address
Emam Reza Sq, Ebne-sina Ave, Emam Reza hospital

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3802 2806

Email
sadata931@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
345 - 91357

Phone
+98 51 3841 2081

Email
ramresearch@mums.ac.ir

Grant name

Grant code / Reference number
951472

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Atena Sadat

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Emam Reza hospital, Emam Reza Sq, Ebne-sina Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3802 2806

Email
sadata931@mums.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Sara Mirzaeian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Ghaem hospital, Ahmad Abad Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699199

Phone
+98 51 3801

Email
mirzaeians@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Atena Sadat

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Emam Reza hospital, Emam Reza Sq, Ebne-sina Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3802 2806

Email
sadata931@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after patients are made unidentifiable

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used
Carrying out analysis on data is permitted.

From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.

Comments