

# 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 infants' 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

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##### Province

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##### Phone

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##### 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

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#### Province

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#### 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

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##### Province

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##### Postal code

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##### Phone

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##### Email

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## 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

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## 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**

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**Province**

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**Postal code**

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**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**