

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the short term outcome of preterm infants with three different umbilical cord clamping methods

Protocol summary

Study aim

The aim of present study is determining the effect of cord milking, delayed and early cord clamping on preterm infant outcome such as intraventricular hemorrhage, bronchopulmonary dysplasia and blood transfusion and to detect the best method of cord clamp in these infants.

Design

In a randomized controlled clinical trial 90 neonates randomly allocate in three groups. Cord clamping performs in three different methods: routine , delayed clamping and cord milking. Enrolled infants follow till discharge to determine their outcome including need to blood transfusion, intraventricular hemorrhage and need to supplemental oxygen.

Settings and conduct

The study is done in Alzahra Hospital, a referral tertiary university hospital. The aid of labor perform cord clamp according random number list. Admission nurse in nursery, the physician that manage the neonates and outcome recorder are blind about patients groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include preterm infants with gestation age 28-30 weeks; birth weight less than 1500 grams. Non- inclusion criteria include Infants with congenital anomalies; placenta previa; decolman; parental refuse or need to immediate maternal or neonatal resuscitation.

Intervention groups

In control group: routine cord clamping is done 10 seconds after birth. In intervention group1: delayed cord clamp is done 30-60 seconds after birth and in intervention group2: cord milking is done from 20 ±2 cm toward the neonate for 20 seconds three times.

Main outcome variables

Intraventricular hemorrhage; Bronchopulmonary dysplasia; Anemia of prematurity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100512003915N22**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1526 2253

Email address

peirovifara@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the short term outcome of preterm infants with three different umbilical cord clamping methods

Public title

the short term outcome of three different umbilical cord clamping methods

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

preterm infants with gestation age less than 28-30 weeks
birth weight less than 1250

Exclusion criteria:

placenta previa decolman need to emergent
resuscitation of mother or neonate parental refuse
congenital anomalies

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Preterm infants randomly allocated in three groups by random number list generator based on their arrive in delivery room.

Blinding (investigator's opinion)

Double blinded

Blinding description

Nurses who admit these infants , the nonatologists who manage the patients in NICU and outcome recorder are blind to groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences. Golgasht St.

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR. TBZMED.REC.1397.1076

Health conditions studied

1

Description of health condition studied

Anemia of prematurity

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intra-ventricular hemorrhage

Timepoint

At 3-5 days after birth and 28 days

Method of measurement

Brain sonography

2

Description

Bronchopulmonary dysplasia

Timepoint

One month after birth and at discharge

Method of measurement

Need to supplemental oxygen based on pulse oxymetry

Secondary outcomes

1

Description

Anemia of prematurity

Timepoint

Discharge

Method of measurement

The numbers of blood transfusions

2

Description

Intra-ventricular hemorrhage

Timepoint

At 3-5 days and at 28 days of birth

Method of measurement

Brain sonography

3

Description

Bronchopulmonary dysplasia

Timepoint

One month after birth

Method of measurement

Need to supplemental oxygen

Intervention groups

1

Description

Intervention group: Delayed cord clamp within 30-60 sec of delivery

Category

Other

2

Description

Intervention group: Cord milking toward neonate from 20 centimeter for 20 seconds 3 times

Category

Other

3

Description

Control group: Routine cord clamp within 10 seconds of delivery

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Sanaz Yasrebi nia

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South Artesh St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Sanaz Yasrebi nia

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Position

Professor

Latest degree

Subspecialist

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No additional data

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available