Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of delayed versus immediate cord clamping on the incidence of intraventricular hemorrhage (IVH) in preterm neonates with gestational age ≤34 weeks in Hafez & Zeynab hospitals from September 2012 to December 2013

Protocol summary

Summary

The goal of the study is to compare the effect of delayed versus immediate cord clamping on incidence of intraventricular hemorrhage(IVH) in preterm neonate and decide the best time for umbilical cord clamping to decrease their prematurity complications. The study is randomized and double blind performed in two centers. Study populations are premature neonates (gestational age is equal to 26-34 weeks). Exclusion criteria are refuse of parents or the obstetrician; severe congenital anomaly; placenta abruption or previa; need for immediate resuscitate in mother or the neonate sample size is calculated as 114 neonates, 57 neonates for case and 57 neonates for control group. Intervention is a 30-45seconds delay in clamping of the umbilical cord after birth in preterm neonate with gestational age of 26-34 weeks , who are kept between mother’s legs in normal vaginal delivery or on mother’s leg during cesarean section (at level of vaginal). Evaluation of IVH is performed by cranial ultrasonography on day 3-4 and day 7-10 after birth and analyzed the result for IVH, hemoglobin, hematocrit, bilirubin. Need for transfusion IVH risk factors and other DCC complications or benefits.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031116936N1**
Registration date: **2014-05-17, 1393/02/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-17, 1393/02/27

Registrant information

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Recruitment status

Recruitment complete

Funding source
Shiraz University Of Medical Science

Expected recruitment start date
2012-08-22, 1391/06/01

Expected recruitment end date
2013-11-22, 1392/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of delayed versus immediate cord clamping on the incidence of intraventricular hemorrhage (IVH) in preterm neonates with gestational age ≤34 weeks in Hafez & Zeynab hospitals from September 2012 to December 2013

Public title

The effect of delayed cord clamping on IVH in premature

neonate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: premature neonates with gestational age 26-34 weeks born in Shiraz Hafez and Hazrat Zeynab hospitals from September 2012 to December 2013
Exclusion criteria: decline to participate; refuse of neonate logiest or obstetrician; severe congenital anomalies; need for immediate resuscitation after birth in neonate or mothers; placenta abruption or placenta previa; umbilical cord clamped in a time other than what is considered.

Age

To **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University Of Medical Science

Street address

Building of Shiraz University Of Medical Science, Zand street, Shiraz

City

Shiraz

Postal code

Approval date

2012-09-13, 1391/06/23

Ethics committee reference number

CT-P-4103

Health conditions studied

1

Description of health condition studied

IVH: Imtraventricular hemorrhage

ICD-10 code

I62.9

ICD-10 code description

Intracranial haemorrhage (nontraumatic), unspecified

Primary outcomes

1

Description

IVH by cranial ultrasonography

Timepoint

3-4 day and7-10 day after intraventricular (birth)

Method of measurement

diagnostic ultrasonography device mindray M7 by volpe criteria according to Neurology of the newborn Ed.5 2008

Secondary outcomes

1

Description

hemoglobin

Timepoint

the first day after intervention

Method of measurement

sismex automated device for blood index

2

Description

hematocrit

Timepoint

the first day after intervention

Method of measurement

sismex automated device for blood index

3

Description

platelet

Timepoint

the first day after intervention and when needed after that

Method of measurement

sismex automated device for blood index

4

Description

bilirubin

Timepoint

2nd,3nd and fifth days after intervention if needed after that up to the discharge time

Method of measurement

By labratory

5

Description
Apgar score
Timepoint
1st and 5th minute after intervention
Method of measurement
according to clinical scoring of neonate by color, tone, reflex, heart rate and respiration

Intervention groups

1

Description
30-45 seconds delay in clamping of umbilical cord
Category
Prevention

2

Description
umbilical cord clamping in10 to15 seconds after birth
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez hospital
Full name of responsible person
Dr. Leila Salarian
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Hafez Hospital, Chamran street, Shiraz
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2

Recruitment center
Name of recruitment center
Zeinabieh Hospital
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Dr.Salarian
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Zeinabieh Hospital, Defae moghadas square, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Dr. Seyed Basir Hashemi
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7th Floor dean of research, Building of University Of Medical Science, Zand street, Shiraz, Fars
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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
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Name of organization / entity
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty