

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Name

Fariba Hemmati

Name of organization / entity

Shiraz University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 1612 5481

Email address

hemmatif@sums.ac.ir

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; refusal 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 and 7-10 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,3rd 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 in 10 to 15 seconds after birth

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Dr. Leila Salarian

Street address

Hafez Hospital, Chamran street, Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Zeinabieh Hospital

Full name of responsible person

Dr. Salarian

Street address

Zeinabieh Hospital, Defae moghadas square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

7th Floor dean of research, Building of University Of Medical Science, Zand street, Shiraz, Fars

City

Shiraz

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

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Namavar Jahromi Bahia

Position

Professor of OB & GYN specialty infertility

Other areas of specialty/work

Street address

OB & GYN department, Shahid faghihi hospital, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 71 1233 2356

Fax

Email

namavarb@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Fariba Hemmati

Position

Professor of Neonatal

Other areas of specialty/work

Street address

Neonatal part, Nemazee Hospital, Zand street, Shiraz

City

Shiraz

Postal code

Phone
+98 71 1612 5479
Fax
Email
hemmatif@sums.ac.ir
Web page address

+98 71 1630 1004
Fax
Email
lilsalaria@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Leila Salarian
Position
Other areas of specialty/work
Street address
Nemazee hospital, Zand street, Shiraz
City
Shiraz
Postal code
Phone

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