Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative Study Of the Effect Of Delayed Versus Early Cord Clamping On The Incidence of Intra Ventricular Hemorrhage In Preterm Neonate

Protocol summary

Summary

In this study, 54 premature infants delivered via cesarean section and gestational age of less 32 weeks and birth weight of less than 1500 gram will randomly assign to two groups. The exclusion criteria are: congenital anomalies, maternal use of medications that interrupt with coagulative system, infant trauma, need for infant intensive resuscitation, twin pregnancy, breech presentation, maternal systemic diseases (preeclampsia, diabetes, hypertension). The cord of 27 infants in the case group will be clamped after 30-45 seconds of birth and 27 infants in control group will have early cord clamping within first 10 seconds of life. All infants will have routine care for premature infants and will be evaluated for Intra ventricular using brain ultrasonography within third to seventh days of life. The rate of IVH will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091319145N1**
Registration date: **2014-12-01, 1393/09/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-01, 1393/09/10

Registrant information

Name
Afshin Khani
Name of organization / entity
Babol University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 11 3219 0971
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afshinkhani@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of research and technology of Babol University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study Of the Effect Of Delayed Versus Early Cord Clamping On The Incidence of Intra Ventricular Hemorrhage In Preterm Neonate

Public title

The Effect Of Delayed Cord Clamping On The Incidence Of Intra Ventricular Hemorrhage

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Premature infants; delivered via cesarean section; Gestational age of less 32 weeks; Birth weight of less than 1500 gram Exclusion Criteria: Congenital anomalies; Maternal use of medications that interrupt with coagulative system; Infant trauma; Need for infant intensive resuscitation; Twin pregnancy; Breech presentation; Maternal systemic diseases (preeclampsia, diabetes, hypertension)

Age

To **7 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz street, Keshvary Square, Babol
City
Babol
Postal code
Approval date
2014-01-21, 1392/11/01
Ethics committee reference number
ژ/پ304709/

Health conditions studied

1

Description of health condition studied
Intra Ventricular Hemorrhage
ICD-10 code
P52.3
ICD-10 code description
Unspecified intraventricular (non-traumatic) hemorrhage of fetus and newborn

Primary outcomes

1

Description
Intra Ventricular Hemorrhage
Timepoint
Days 3 to 7
Method of measurement
Brain Ultrasonography

2

Description
Survival of the infant
Timepoint
Every day up to 28 days
Method of measurement
Observing the neonate

Secondary outcomes

empty

Intervention groups

1

Description
Case: Cord clamping within 30 to 45 seconds of life
Category
Prevention

2

Description
Control: Cord clamping in the first 10 seconds of life
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Mobina Vrij Kazemi
Street address
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Aliakbar Moghadamnia
Street address
Deputy of Research and Technology, Babol University of Medical Sciences
City
Babol
Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Mobina Vrijkazemi

Position

Nurse

Other areas of specialty/work

Street address

NICU ward, Ayatollah Rouhani Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohsen Haghshenas

Position

Neonatologist (MD)

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Afshin Khani

Position

Student

Other areas of specialty/work

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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