

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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

Email address

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

/304709پ/ژ

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

City
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+98 11 3223 8290

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baroon.vk@gmail.com

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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

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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