

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Prophylactic intravenous Indomethacin effect in decreasing symptomatic Patent Ductus Arteriosus (PDA) and assisted ventilation

Protocol summary

Tabriz University of Medical Sciences and Health Services

Summary

We enrolled 70 neonates with gestational age equal or below than 32 w and birth weight 800-1500 g and divided them with rand list software in two groups. In intervention group we used iv indomethacin (35 neonates) then two groups were evaluated with echocardiography in 4th day and transcranial sonosgraphy in 7th day and other complications were compared between two groups.

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

PDA

IRCT registration information

IRCT registration number: **IRCT201107117010N1**

Registration date: **2011-10-17, 1390/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-17, 1390/07/25

Registrant information

Name

Mahmood Samadi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

samadima@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Scientific title

Prophylactic intravenous Indomethacin effect in decreasing symptomatic Patent Ductus Arteriosus (PDA) and assisted ventilation

Public title

Closure of venous that remained patent from fetal duration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: birth in Alzehra hospital and gestational age equal or lower than 32 week; birth weight equal or between 800-1500g. Exclusion criteria: congenital anomaly; severe asphyxia; thrombocytopenia(plt<50000); creatinine >1.8mg\dl; bleeding tendency; mother consumption of indomethacine.

Age

To **1** year old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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**

Tabriz University of Medical Sciences and Health Services

Street address

Golgasht avenue

City

Tabriz

Postal code**Approval date**

2010-08-20, 1389/05/29

Ethics committee reference number

5\4\2573

Health conditions studied**1****Description of health condition studied**

Patent Ductus Arteriosus

ICD-10 code

Q25.0

ICD-10 code description

Persistent ductus arteriosus

Primary outcomes**1****Description**

Decreasing symptomatic PDA (severity of PDA)

Timepoint

4 days

Method of measurement

Echocardiography

Secondary outcomes**1****Description**

Decreasing assisted ventilation

Timepoint

First 14 days of birth

Method of measurement

Visit

Intervention groups**1****Description**

Intervention group: Intravenous (IV) indomethacin at 2-12 first hours with dosage of 0.2mg/kg and then 0.1mg/kg after 24 and 48 hours

Category

Treatment - Drugs

2**Description**

Control group: without any intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzehra hospital

Full name of responsible person

Dr Mahmood Samadi, associated professor

Street address

Alzehra hospital, Artesh avenue

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences and Health Services

Full name of responsible person

Dr Alireza Ostad Rahimi

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Vice chancellor for research, Tabriz University of Medical sciences, Daneshgah Avenue

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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 and Health Services

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***Postal code****Phone**

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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*