Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of oral Ibuprofen and intravenous indomethacin for the treatment of patent ductus arteriosus in preterm infants

Protocol summary

Summary

Objective: To compare the effectiveness and complications of ibuprofen versus indomethacin treatment of patent ductus arteriosus in preterm infants. Inclusion criteria: Gestational age between 29 weeks and six days to 35 weeks and six days, Between 1000 and 2500 gr birth weight, Age 72 to 120 hours after birth. Exclusion criteria:Congenital heart disease, Life-threatening infection, Liver failure, Severe intracranial hemorrhage. Sample size:40 infants per group Manipulation:To a group of patients prescribed ibuprofen and indomethacin groups. Time of manipulation:24 and 48 hours after birth Primary outcome: Closure of patent ductus arteriosus

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111024977N1**
Registration date: **2015-12-16, 1394/09/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-16, 1394/09/25

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Qom University of Medical Sciences

Expected recruitment start date

2014-08-22, 1393/05/31

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral Ibuprofen and intravenous indomethacin for the treatment of patent ductus arteriosus in preterm infants

Public title

Comparison of oral Ibuprofen and intravenous indomethacin for the treatment of patent ductus arteriosus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age between 29 weeks and six days to 35 weeks and six days; Between 1000 and 2500 gr birth weight; Age 72 to 120 hours after birth. Exclusion criteria:Congenital heart disease; Life-threatening infection; Liver failure; Severe intracranial hemorrhage.

Age

From **1 day** old to **31 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Qom University of Medical Sciences

Street address

Qom, Saheli Street, Qom University of Medical Sciences

City

Qom

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

138

Health conditions studied

1

Description of health condition studied

Patent Ductus Arteriosus

ICD-10 code

Q25.0

ICD-10 code description

Patent ductus arteriosus

Primary outcomes

1

Description

Thrombocytopenia

Timepoint

72 hours after intervention

Method of measurement

blood test

2

Description

Pulmonary hemorrhage

Timepoint

72 hours after intervention

Method of measurement

Examination and chest radiography

3

Description

Increased creatinine

Timepoint

72 hours after intervention

Method of measurement

blood test

4

Description

Increased bilirubin

Timepoint

72 hours after intervention

Method of measurement

blood test

Secondary outcomes

1

Description

Closure of patent ductus arteriosus

Timepoint

72 hours after intervention

Method of measurement

Using echocardiography

Intervention groups

1

Description

In the intervention group Type of treatment:Treatment with ibuprofen Dose: 10 mg per kg and then to 5 mg kg at 24 and 48 hours after birth

Category

Treatment - Drugs

2

Description

In the comparison group Type of treatment:Treatment with Indomethacin Dose: 0.2 milligrams per kilogram at 24 and 48 hours after birth

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ezadi Hospital

Full name of responsible person
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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Saheli St, University of Medical Sciences, Qom

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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
Qom 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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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