

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus (PDA) in kosar Hospital-Iran

Protocol summary

Summary

OBJECTIVE: Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus (PDA). **Type of Study:** Double Blinded Clinical Trial with Randomized Controls. **Methodology & Research Design:** A. **Study Sample:** Premature infants with patent ductus arteriosus (PDA) (borned in Kosar Hospital-Iran). **o Inclusion Criteria:** Gestational age less than or equal to 34 weeks; Birth elapsed time less than or equal to 14 days; PDA diagnosis based on echocardiography findings. **o Exclusion Criteria:** Any type of congenital heart disease is to keep the blood flow needed PDA; Life-threatening infections; Grade 3-4 intraventricular hemorrhage (within recent 24 hours); Urinary output less than 1mg/kg/h in last 8 hours; Serum creatinine level higher than 88 μmol/L; platelet counts less than 109×50 per liter; Hyperbilirubinemia requiring blood transfusions; Active necrotizing enterocolitis or bowel perforation; Liver dysfunction; Gastrointestinal bleeding; Retinopathy; Bronchopulmonary dysplasia; Lack of parental consent. **o Sample Size:** At least 53 patients per group. **B. Investigated intervention/s:** The first group of patients treated with ibuprofen at a dose of 10 mg/kg/stat and then 5 mg/kg/12h to two doses, and the second group of patients treated with acetaminophen for two days at a dose of 15 mg/kg/6h (8 doses). **C. Intervention time:** The first 14 days of life. **D. The primary outcome or consequences of the study:** Echocardiographic findings indicate that closure of PDA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120425357N1**

Registration date: **2015-12-20, 1394/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-20, 1394/09/29

Registrant information

Name

Tahereh Jangjoo Pirbazari

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2015-12-07, 1394/09/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus (PDA) in kosar Hospital-Iran

Public title

Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Gestational age less than or equal to 34 weeks; Birth elapsed time less than or equal to 14 days; PDA diagnosis based on echocardiography findings.

Exclusion Criteria: Any type of congenital heart disease is to keep the blood flow needed PDA; Life-threatening infections; Grade 3-4 intraventricular hemorrhage (within recent 24 hours); Urinary output less than 1mg/kg/h in last 8 hours; Serum creatinine level higher than 88 µmol/L; platelet counts less than 109×50 per liter; Hyperbilirubinemia requiring blood transfusions; Active necrotizing enterocolitis or bowel perforation; Liver dysfunction; Gastrointestinal bleeding; Retinopathy; Bronchopulmonary dysplasia; Lack of parental consent.

Age

From **1 day** old to **14 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

N/A

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

Qazvin University of Medical Sciences - Children's Hospital in Qods

Street address

Qods Square

City

Qazvin

Postal code

Approval date

2014-12-31, 1393/10/10

Ethics committee reference number

20/9885/3

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

heart murmur

Timepoint

Before intervention - three days after the intervention.

Method of measurement

Auscultation - Echocardiography

Secondary outcomes

1

Description

Bleeding Including the gastrointestinal tract, urinary tract and respiratory tract

Timepoint

During the intervention

Method of measurement

Clinical observation and tests such as analysis of urine and faeces

Intervention groups

1

Description

The first group of patients treated with ibuprofen at a dose of 10 mg/kg/stat and then 5 mg/kg/12h to two doses.

Category

Treatment - Drugs

2

Description

The second group of patients treated with acetaminophen for two days at a dose of 15 mg/kg/6h (8 doses).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital Qazvin

Full name of responsible person

Tahereh Jangjoo Pirbazri

Street address

Vali Asr intersection - Taleghani Avenue

City

Qazvin

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

Qazvin University of Medical Sciences

Full name of responsible person

Abolfazi Mahyar

Street address

Qazvin -Street Shahid Bahonar

City

Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin 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**

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Full name of responsible person

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esmail.jangjoo@gmail.com**Web page address****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