

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A clinical trial comparing the effects of two different brands of ibuprofen (Pedia and Ibuprofen) on ductus arteriosus closure in premature infants with patent ductus arteriosus

Protocol summary

Study aim

Comparing the effects of two different brands of ibuprofen (Pedia and Ibuprofen) on ductus arteriosus closure in premature infants with patent ductus arteriosus

Design

Two-arm paralleled phase 3 trial without blinding and randomization.

Settings and conduct

A non-blinded study will be conducted in the pediatric department of Valiasr Hospital in Birjand. One group will receive Pedia, the French brand of ibuprofen produced by Orphan pharmaceutical company, while the other group will receive the Iranian form of ibuprofen, which is a generic version produced by Caspian Tamin Pharmaceutical Company. Both groups will receive intravenous injections of the medicine. The first day's dose will be 10 mg/kg, followed by 5 mg/kg after 24 hours, and another 5 mg/kg 24 hours later. The study will involve 160 patients who will be divided into two groups, with the first 80 receiving intervention from Group 1 and the subsequent 80 receiving intervention from Group 2.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: Preterm newborn and size of patent ductus arteriosus that responds to drug therapy. Major exclusion criteria: the presence of underlying heart diseases, major congenital anomalies, and life-threatening sepsis.

Intervention groups

Intervention group 1 (French Ibuprofen): Ibuprofen from the French pharmaceutical company ORPHAN, Pedia brand, will be injected intravenously at doses of 10 mg/kg on the first day, 5 mg/kg 24 hours later, and 5 mg/kg 24 hours later (the last dose). Intervention group 2 (Iranian Ibuprofen): Ibuprofen from the Iranian Caspian Tamin Pharmaceutical Company, under the Ibuprofen generic name, will be injected intravenously at doses of

10 mg/kg on the first day, 5 mg/kg 24 hours later, and 5 mg/kg 24 hours later (the last dose).

Main outcome variables

Ductus arteriosus closure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N48**

Registration date: **2023-05-15, 1402/02/25**

Registration timing: **prospective**

Last update: **2023-05-15, 1402/02/25**

Update count: **0**

Registration date

2023-05-15, 1402/02/25

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-05, 1402/03/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effects of two different brands of ibuprofen (Pedeia and Ibuprofen) on ductus arteriosus closure in premature infants with patent ductus arteriosus

Public title

Effects of two different brands of ibuprofen on ductus arteriosus closure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm newborn A size of patent ductus arteriosus that responds to drug therapy Gestational age of 32 weeks or more Birth weight 1500 grams and less Age between 3 and 15 days

Exclusion criteria:

Presence of underlying heart diseases Major congenital anomalies Life-threatening sepsis Renal failure Pulmonary hemorrhage Thrombocytopenia below 60,000/mm³

Age

From **3 days** old to **15 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Not 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**

Ethics Committee of Birjand University of Medical

Sciences

Street address

Birjand University of Medical Sciences, Ayatollah Ghaffari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-03-02, 1397/12/11

Ethics committee reference number

lr.bums.REC.1397.325

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**

Ductus arteriosus closure

Timepoint

Prior to treatment initiation and three days post-treatment completion

Method of measurement

Echocardiography

Secondary outcomes

empty

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

Intervention group 1 (French Ibuprofen/Pedeia): Ibuprofen from the French pharmaceutical company ORPHAN, Pedeia brand, will be injected intravenously at doses of 10 mg/kg on the first day, 5 mg/kg 24 hours later, and 5 mg/kg 24 hours later (the last dose).

Category

Treatment - Drugs

2**Description**

Intervention group 2 (Iranian Ibuprofen): Ibuprofen from the Iranian Caspian Tamin Pharmaceutical Company, under the Ibuprofen generic name, will be injected intravenously at doses of 10 mg/kg on the first day, 5

mg/kg 24 hours later, and 5 mg/kg 24 hours later (the last dose).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital's Pediatrics Department

Full name of responsible person

Alireza Taghizadegan

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Ghaffari Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery for Research, Birjand University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Miri

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Vice-chancellory for Research, Birjand University of Medical Sciences, Ayatollah Ghafari Street,

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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

Vice-chancellery for Research, Birjand University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Alireza Taghizadegan

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Dr. Forud Salehi

Position

Pediatric cardiologist

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mohammad Bagher Roozgar

Position

Translator

Latest degree

Master

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set and other information related to research methodology

When the data will become available and for how long

After the paper extracted from the project is published and for 6 months ever since

To whom data/document is available

Researchers

Under which criteria data/document could be used

Research purposes

From where data/document is obtainable

Corresponding author

What processes are involved for a request to access data/document

Personal email to the corresponding author of the extracted article

Comments