Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial comparing the effects of two different brands of ibuprofen (Pedea 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 (Pedea 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 Pedea, 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, Pedea 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

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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 (Pedea 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
۹۷۱۷۸۵۳۵۷۷
Approval date
2019-03-02, 1397/12/11
Ethics committee reference number
Ir.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/Pedea): Ibuprofen from the French pharmaceutical company ORPHAN, Pedea 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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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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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 Practirtioner

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Subspecialist

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Cardiology

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Translator

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Master

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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