Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effect of oral ibuprofen for patent ductus arteriosus closure in infants

Protocol summary

Summary

Patent ductus arteriosus is a great way communication normally open to the fetus and Main artery that connects the pulmonary trunk to the descending aorta and the main part of the right ventricle into the lungs causes the blood to be transported to the systemic circulation. Patent ductus arteriosus remains open lead to symptoms such as distance increases systolic and diastolic pressure, pulse, filling or bonding, increased need for oxygen, pulmonary edema, tachycardia, Kvrdyvm blades are activated and eventually right heart failure. The aim of this study was to evaluate the efficacy of oral ibuprofen to close patent ductus arteriosus in neonates is. The purpose of this clinical trial, infants with patent ductus arteriosus and Taleghani Hospital of Kabir the total of 60 neonates with patent ductus arteriosus according to criteria (term neonates born ≥ 3 days of age, proof of patent ductus arteriosus by echocardiography) and randomly assigned to two groups (mg/kg20 as an initial dose of oral ibuprofen and mg/kg10 every 24 hours for two days) and control (mg/kg10 as an initial dose of oral ibuprofen and mg/kg5 every 24 hours for two days) groups. 24 hours and 2 weeks after the third dose drug echocardiography and the results are recorded. Finally, the results between the two groups were analyzed using SPSS statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102215113N1**
Registration date: **2013-12-04, 1392/09/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-12-04, 1392/09/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2013-08-21, 1392/05/30

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral ibuprofen for patent ductus arteriosus closure in infants

Public title

Effect of oral ibuprofen for patent ductus arteriosus closure in infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:term infants (gestational age 37-42 weeks); Life Age ≥ 3 days of patent ductus arteriosus by echocardiography ; Proof of completion of an informed consent form Exclusion criteria: There is a reluctance to participate in the study ; Contraindications including

ibuprofen creatinine> 8/1; platelet count less than 50,000 ;active gastrointestinal hemorrhage or intraventricular hemorrhage (confirmed by ultrasound); Antrkvlyt necrosis and sepsis; patent ductus arteriosus associated with other disorders; such as TORCH (intrauterine infection).

Age
From **1 year** old to **3 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University Medical Sciences

Street address
Hoda Elm Street, Amirkabir, Arak

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arak

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Approval date
2013-08-21, 1392/05/30

Ethics committee reference number
92-151-14

Health conditions studied

1

Description of health condition studied
Closure of patent ductus arteriosus

ICD-10 code
Q25.0

ICD-10 code description
patent dactus arterioussus

Primary outcomes

1

Description
Gastrointestinal bleeding

Timepoint
Before treatment - after each drug administration.

Method of measurement
Blood

2

Description
Platelet count

Timepoint
Before treatment - after each drug administration.

Method of measurement
Blood

Secondary outcomes

1

Description
Serum creatinine

Timepoint
Before treatment - after each drug administration.

Method of measurement
blood

Intervention groups

1

Description
Case Groups: mg/kg20 oral ibuprofen as an initial dose every 24 hours for two days will receive mg/kg10.

Category
Treatment - Drugs

2

Description
Control group: mg/kg10 oral ibuprofen as an initial dose every 24 hours for two days and mg/kg5 will receive.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir Hospital Arak

Full name of responsible person
Dr. Soltani Manuchehr

Street address

City
arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
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Dr.davood hekmatpoo
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Hoda Elm Street, Hospital Amirkabir, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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