Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of intravenous ibuprofen versus intravenous paracetamol on the occlusion of patent ductus arteriosus in preterm infants: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of intravenous ibuprofen versus intravenous paracetamol on the occlusion of patent ductus arteriosus in preterm infants

Design

This is a single-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible preterm infants with patent ductus arteriosus will refer to Fatemieh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group. This trial will be single-blinded so that infants will be not aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age equal to or less than 37 weeks, The past time after birth equal to or less than 14 days, Patent ductus arteriosus Exclusion criteria: Infectious disease, Hyperbilirubinemia needing transfusion, Active necrotizing enterocolitis or intestinal perforation, Liver function disorder, Any hemorrhagic disorder, Retinopathy, Bronchopulmonary dysplasia, Platelet deficiency

Intervention groups

Intervention group: Intravenous ibuprofen (manufactured by Caspian Tamin Pharmaceutical Company) first 10 mg/kg then 5 mg/kg every 12 hours for 3 days Control group: Intravenous paracetamol (manufactured by Caspian Tamin Pharmaceutical Company) 15 mg/kg every 6 hours for 3 days

Main outcome variables

Primary outcome: The occlusion of patent ductus arteriosus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N321**
Registration date: **2019-12-10, 1398/09/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-10, 1398/09/19**
Update count: **0**

Registration date

2019-12-10, 1398/09/19

Registrant information

Name
Jalal Poorolajal
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-24, 1398/09/03

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous ibuprofen versus intravenous paracetamol on the occlusion of patent ductus arteriosus in preterm infants: a single-blind randomized clinical trial

Public title

Effect of intravenous ibuprofen versus intravenous paracetamol on the occlusion of patent ductus arteriosus in preterm infants: a single-blind randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age equal to or less than 37 weeks, The past time after birth equal to or less than 14 days, Patent ductus arteriosus

Exclusion criteria:

Infectious disease, Hyperbilirubinemia needing transfusion, Active necrotizing enterocolitis or intestinal perforation, Liver function disorder, Any hemorrhagic disorder, Retinopathy, Bronchopulmonary dysplasia, Platelet deficiency

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The infants will be unaware of the type of intervention. Thus, the trial will be run as single-blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.UMSHA.REC.1398.675

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

The occlusion of patent ductus arteriosus

Timepoint

Three days after that

Method of measurement

Through echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravenous ibuprofen (manufactured by Caspian Tamin Pharmaceutical Company) first 10 mg/kg then 5 mg/kg every 12 hours for 3 days

Category

Treatment - Drugs

2

Description
Control group: Intravenous paracetamol (manufactured by Caspian Tamin Pharmaceutical Company) 15 mg/kg every 6 hours for 3 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital in Hamadan city
Full name of responsible person
Dr Mayam Zeinali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
Hamedan 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
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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available