

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 Fatemeh 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

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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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

Hamadan

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

Street address

Fatemieh Hospital, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mayam Zeinali

Position

Resident of Pediatrics

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Kazem Sabzei

Position

Podiatrist

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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