

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of the efficacy of oral Acetaminophen and oral Ibuprofen for treatment of preterm with patent ductus arteriosus

#### Protocol summary

The closure of the ductus arteriosus (complete, incomplete, unchanged)

#### Study aim

Comparison of the efficacy of oral Acetaminophen and oral Ibuprofen for treatment of preterm with patent ductus arteriosus

#### Design

A clinical trial with parallel groups, single-blinded, randomized (permuted block randomization), phase 3 on 60 newborns, using www.sealedenvelope.com for randomization

#### Settings and conduct

This interventional study will be conducted from April to Nov 2020. A total of 60 preterm neonates with diagnosis of PDA admitted in NICU of Akbar Abadi Hospital Tehran were selected. Neonates are randomly assigned to two groups. In the first intervention group, oral Acetaminophen is given every 8 hours at a dose of 15 mg/kg for 3 days. In the second intervention group, oral Ibuprofen every 8 hours at a dose of 10 mg/kg for 3 days.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Parent's consent to participate in the study, Gestational age 26 to 37 weeks, Diagnosis of ductus arteriosus based on echocardiographic evidence at 24 to 72 hours after birth. Exclusion criteria: Premature newborn with fever and seizure, Life-threatening infections, Clinical or radiographic evidence of necrotizing enterocolitis Evidence of bleeding, Platelets less than 50,000 per ml Liver failure , Congenital brain-neurological disorders, Metabolic and genetic syndromes, Pulmonary hypoplasia syndrome, Congenital heart anomalies or other fatal abnormalities

#### Intervention groups

Total of 30 neonates in the first intervention group and 30 neonates in the second intervention group. In the first intervention group, oral Acetaminophen is taken every 8 hours at a dose of 15 mg/kg for 3 days. In the second intervention group, oral Ibuprofen is taken every 8 hours at a dose of 10 mg/kg for 3 days.

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211010052715N1**

Registration date: **2021-11-25, 1400/09/04**

Registration timing: **retrospective**

Last update: **2021-11-25, 1400/09/04**

Update count: **0**

##### Registration date

2021-11-25, 1400/09/04

##### Registrant information

##### Name

Zahra Hadadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2304 6253

##### Email address

hadadi.za@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-11-06, 1400/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the efficacy of oral Acetaminophen and oral Ibuprofen for treatment of preterm with patent ductus arteriosus

**Public title**

Comparison of the efficacy of oral Acetaminophen and oral Ibuprofen for treatment of preterm with patent ductus arteriosus

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Parent's consent to participate in the study Gestational age 26 to 37 weeks Diagnosis of ductus arteriosus based on echocardiographic evidence at 24 to 72 hours after birth

**Exclusion criteria:**

Premature newborn with fever and seizure Life-threatening infections, Clinical or radiographic evidence of necrotizing enterocolitis Evidence of bleeding Platelets less than 50,000 per ml Liver failure Congenital brain-neurological disorders, Metabolic and genetic syndromes Pulmonary hypoplasia syndrome Congenital heart anomalies or other fatal abnormalities

**Age**

From **1 day** old to **3 days** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the block randomization method is used with blocks of sizes 4 , 6 and 8. The website <https://www.sealedenvelope.com> is used to create a randomization list. The blocks are randomly selected using this website and given to a researcher who is not involved in choosing the type of drug. Each random chain generated contains a unique code for concealment. The drug regimen is placed in envelopes according to random chains, and after sealing it on the envelopes, the specific number created by the site is written and the envelopes are randomly placed in a box. a box.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is single-blinded and patients are unaware of the type of medication received. How to blind patients: Acetaminophen and Ibuprofen are both taken orally and given to infants 1-3 days old with a dropper.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Hemat highway next to the Milad tower.

**City**

Tehran

**Province**

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**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2021-04-12, 1400/01/23

**Ethics committee reference number**

IR.IUMS.FMD.REC.1400.050

**Health conditions studied****1****Description of health condition studied**

Patent ductus arteriosus (PDA)

**ICD-10 code**

Q25.0

**ICD-10 code description**

Patent ductus arteriosus

**Primary outcomes****1****Description**

PDA size

**Timepoint**

Before and after the intervention

**Method of measurement**

Echocardiography by pediatric's cardiologist .

**Secondary outcomes**

empty

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

Intervention group: Includes premature neonates with

PDA diagnosis by pediatric cardiologist. In this group, samples (n=30) received oral Acetaminophen at a dose of 15mg / kg every 8 hours for 3 days.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Includes premature neonates with PDA diagnosis by pediatric cardiologist. In this group, samples (n=30) received oral Ibuprofen at a dose of 10mg / kg every 8 hours for 3 days.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Akbar Abadi Hospital

**Full name of responsible person**

Zahra Hadadi

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Molavi St, Molavi (cross)

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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**Full name of responsible person**

Hosein Keivani

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Shahid Hemmat Highway next to the Milad tower, Iran  
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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Zahra Hadadi

**Position**

Specialty

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

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Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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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

Not applicable

### 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

Not applicable

### Data Dictionary

Not applicable