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

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

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

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
Tehran

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 pediatiric'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

Street address

Molavi St, Molavi (cross)

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran 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

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

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Full name of responsible person

Semira Mehralizadeh

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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
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