

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of parenteral Acetaminophen and oral Ibuprofen on the treatment of patent ductus arteriosus in premature infants with very low weight

Protocol summary

Study aim

Comparison of the effects of injectable acetaminophen and oral ibuprofen in the treatment of patent ductus arteriosus in very low birth weight premature infants

Design

A clinical trial with two intervention groups

Settings and conduct

The study will be conducted in newborns hospitalized in NICU and neonatal ward in Shahid Motahari and Kausar hospitals in Urmia city of Iran. Babies will be divided into two groups using the data randomization table. And two different medications will be prescribed for each group and a comparison will be made between the response to the treatment and the side effects of the treatment between these two groups.

Participants/Inclusion and exclusion criteria

Infants with a gestational age of less than 32 weeks and a birth weight of less than 1500 grams

Intervention groups

In this study, we have two groups of neonates with open ductus arteriosus, one group of them will receive injectable acetaminophen at a dose of 15 mg per kilogram of body weight every six hours for three days and for the other group we will give oral ibuprofen at a dose of 10 mg per kilogram of body weight daily for three days

Main outcome variables

The size of the patent ductus arteriosus and its size after the use of the two mentioned treatments, the incidence of complications mentioned in different treatments such as bleeding and increased liver enzymes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230828059282N1**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **registered_while_recruiting**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

Shadi Irankhah Shiraz

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 902 229 0322

Email address

shirankhahsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-25, 1402/04/04

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of parenteral Acetaminophen and oral Ibuprofen on the treatment of patent ductus arteriosus in premature infants with very low weight

Public title

Acetaminophen vs Ibuprofen in treatment of patent ductus arteriosus in premature infants with very low weight

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Prematurity Not physiologically closed patent ductus arteriosus Very low weight

Exclusion criteria:

Sepsis

Age

To **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used, so that at first all the possible states of the combination AABB will be listed, then according to the sample size (40) and the block size equal to 4, 10 blocks will be randomly selected. will be selected. The selection of randomization will be such that first all possible combinations of 4 will be listed and a code will be assigned for each, and then 10 blocks will be selected and listed in order, and the allocation of people will be based on this list. The codes will be secret and only available to the epidemiological consultant. All steps will be done under the supervision of an epidemiologist and using Random Allocation software, version one.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of urmia university of medical sciences

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No. 12,7th alley.,Resalat ave.,Urmia,West Azarbayjan,Iran

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Postal code

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Approval date

2023-06-24, 1402/04/03

Ethics committee reference number

IR.UMSU.REC.1402.094

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**

Closed ductus arteriosus

Timepoint

3,6,9,12 days from initial treatment

Method of measurement

Echocardiography

Secondary outcomes

empty

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

Intervention group: IV Acetaminophen 15mg/kg/Q6h

Category

Treatment - Drugs

2**Description**

Intervention group:Oral Ibuprofen suspension 100mg/5ml with 10mg/kg/daily

Category

Treatment - Drugs

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

Motahari hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Saber Qolizade
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research@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
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Position

Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further info

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available