Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 medication 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 neonate 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 physiologicaly 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
Street address
No. 12,7th alley.,Resalat ave.,Urmia,West Azarbayjan,Iran
City
Urmia
Province
West Azarbaijan
Postal code
5714774581
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 suspansion 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

Shadi Irankhah Shiraz
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NO.1,Kashani Ave.
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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
Street address
NO.1,Resalat Ave.,Urgance Ave
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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
Shadi Irankhah Shiraz
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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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