Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Oral acetaminophen versus paracetamol in the preterm with persistent patent ductus arteriosus admitted to the neonatal intensive care unit of Imam Reza (AS) Hospital in Mashhad

Protocol summary

Study aim
Comparison of the effectiveness of oral acetaminophen versus paracetamol in the preterm with persistent patent ductus arteriosus

Design
This study will be performed as a clinical trial design with parallel groups with control group, double-blind, randomized phase 3 on 100 infants; Random number table was used for randomization using www.randomization.com.

Settings and conduct
Seventy premature infants admitted to NICU of Imam Reza Hospital with a gestational age of 37 weeks and less or weighing 2000 g or less with an open arterial canal with clinically significant symptoms and echocardiography will be included in the study. One group received intravenous acetaminophen and the intervention group received oral acetaminophen. Those patients who do not respond to two courses of drug treatment will be candidates for surgical treatment. At the end of treatment, efficacy will be compared based on echocardiographic findings and clinical signs and possible drug side effects, comorbidities, and mortality. This blind two-way study (evaluator and analyst) will be performed

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Premature infants with diagnosis of open arterial duct 2. Parents' consent 3. Gestational age 37 weeks and less 4- weight 2000 grams and less than 2000 gram Exclusion criteria: 1. congenital heart disease that requires PDA 2. Liver disease 3. Active necrotizing enterocolitis or intestinal perforation 4. Gastrointestinal bleeding

Intervention groups
The control group received standard treatment (intravenous acetaminophen) and the intervention group received paracetamol.

Main outcome variables
The rate of arterial duct closure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140907019076N3**
Registration date: **2021-09-29, 1400/07/07**
Registration timing: **retrospective**

Last update: **2021-09-29, 1400/07/07**
Update count: **0**

Registration date
2021-09-29, 1400/07/07

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 915 261 7030
Email address
saeedir@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2021-03-20, 1399/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Oral acetaminophen versus paracetamol in the preterm with persistent patent ductus arteriosus admitted to the neonatal intensive care unit of Imam Reza (AS) Hospital in Mashhad

Public title
Oral acetaminophen versus paracetamol in the preterm with persistent patent ductus arteriosus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Preterm newborns with persistent patent ductus arteriosus by echocardiography pediatric cardiologist Parents' consent Gestational age less than 37weeks Birth weight less than 2000 gr

Exclusion criteria:
Congenital heart disease that requires Patent ductus arteriosus (PDA) Liver diseases Active necrotizing enterocolitis or intestinal perforation Gastrointestinal bleeding

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The study design is done in parallel in which the two groups are compared over time. Method used to generate a random allocation sequence using the name of the software or site used: Table of random numbers using the site www.randomization.com The type of randomization is simple and the method of concealment is in the form of sealed envelopes.

Blinding (investigator's opinion)
Double blinded

Blinding description
The evaluator and analyst will be unaware of the case and control groups. Patients will be blinded to the type of intervention and the researcher who must enter the data into the relevant checklist will be blinded to the type of intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhdad University of Medical Sciences

Street address
Central building of Mashhad University of Medical Sciences (Ghorsi), Daneshgah 16, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2020-08-18, 1399/05/28

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1399.342

Health conditions studied

1

Description of health condition studied
Patent ductus arteriosus

ICD-10 code
Q25.0

ICD-10 code description
Patent ductus arteriosus neonates

Primary outcomes

1

Description
Persistent patent ductus arteriosus

Timepoint
Echocardiography before treatment and after treatment for 24 hours

Method of measurement
IPX7 echocardiography device with CA1-7AD curve probe is used for echocardiography.

Secondary outcomes

1

Description
Arterial duct closure time

Timepoint
After the end of treatment

Method of measurement
Echocardiography

2

Description
Number of courses of treatment
Timepoint
After diagnosis, it is treated for three days and if necessary, a three-day period is repeated.
Method of measurement
Echocardiography

3

Description
Medication side effects
Timepoint
Throughout the treatment and after the end of treatment
Method of measurement
Clinical signs and lab tests

4

Description
Comorbidities and mortality
Timepoint
During treatment
Method of measurement
Clinical signs and lab tests

Intervention groups

1

Description
Intervention group: 15 mg / kg prakid acetaminophen drop (100 mg/ml) will prescribed every 6 hours for 3 days and 15 mg / kg intravenous acetaminophen every 6 hours for 3 days.
Category
Treatment - Drugs

2

Description
Control group: Caspian Iranian intravenous acetaminophen at a dose of 15 mg / kg every 6 hours for 3 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Atiyeh Eshkil
Street address
Neonatal Intensive care unite, Imam Reza hospital, Ibn Sina Ave, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
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Mashhad University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Atiyeh Eshkil
Position
physician
Latest degree
Medical doctor
Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published

To whom data/document is available
Data can be accessible through an email to the corresponding author

Under which criteria data/document could be used
Data will be available for researchers in universities and other scientific institute.

From where data/document is obtainable
After sending a request email to the corresponding author, data will be sent in 1 month

What processes are involved for a request to access data/document
Carrying out analysis on data is permitted

Comments