

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 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 Mashhad University of Medical Sciences

Street address

Central building of Mashhad University of Medical Sciences (Ghors), 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

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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ramresearch@mums.ac.ir

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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Person responsible for updating data

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Name of organization / entity
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Atiyeh Eshkil
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Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address

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