

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of oral Acetaminophen with oral Ibuprofen in closure of Patent ductus arteriosus (PDA) in preterm neonate with gestational age less than 32 weeks

Protocol summary

Study aim

Comparison the effect of oral acetaminophen and oral ibuprofen in closing of Patent Ductus Arteriosus (PDA) in preterm neonate with gestational age less than 32 weeks in esfahan

Design

Two parallel randomized clinical trial and randomly divided into two groups of 20 patient and result will analysed double blinded.

Settings and conduct

This study was conducted at NICU of Al-Zahra and Shahid Beheshti hospitals of esfahan city and a neonatal nursing and cardiologist that was in charge of clinical follow-up was not aware of the type of drug used in the course of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: neonates with gestational age less than 32 weeks and a maximum age of 14 days and PDA has been confirmed by echocardiography. Exclusion criteria: neonates with chromosomal anomalies and congenital heart disease and clinical conditions Ibuprofen is contraindicated to start.

Intervention groups

In the first group, oral Acetaminophen is given at a dose of 15 mg / kg every 6 hours for 48 hours, given through the NG tube or through the dropper by a trained nurse. In the second group, oral Ibuprofen is given as 10 mg / kg on the first day and then 5 mg / kg at 24 and 48 hours, followed by a dropper or NG tube.

Main outcome variables

In this study, the effect of Acetaminophen on Patent ductus arteriosus, the duration of hospitalization and the complications of its use are investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170801035441N1**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

Registration date

2018-07-09, 1397/04/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3335 5881

Email address

m.ghaderian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral Acetaminophen with oral Ibuprofen in closure of Patent ductus arteriosus (PDA) in

preterm neonate with gestational age less than 32 weeks

Public title

"Evaluation of the effect of oral acetaminophen on the treatment of neonatal PDAs"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All neonate with 32 weeks or less requiring PDA treatment for clinical conditions PDA is confirmed by echocardiography Age less than 14 days

Exclusion criteria:

Congenital heart disease Clinical and laboratory symptoms of sepsis Chromosomal or congenital abnormalities The presence of Ibuprofen is contraindicated

Age

From **1 day** old to **14 days** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, neonates in need of treatment will be divided into two groups using random numbers and each group will receive standard treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, nursing staff have no information about type of treatment. Only protocol 1 and 2 were recorded in follow-up treatment, so the next assessment was blinded by cardiology services, and it was only during the analysis of these protocols that the type of treatment was identified.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of isfahan University of Medical

Sciences

Street address

Isfahan University of Medical Sciences and Health Services, hezar Jereyb St.

City

isfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2018-03-07, 1396/12/16

Ethics committee reference number

396994

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

The closure rate of patent ductus arteriosus (PDA)

Timepoint

Echocardiography at the beginning of the study and then 48-72 hours after treatment

Method of measurement

Confirmed by echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 48 hours, Drop of Acetaminophen made by the kimia gar Pharma Company at a dose of 15 mg / kg every 6 hours, given through the NG tube or through the dropper, by a nurse trained in neonates.

Category

Treatment - Drugs

2

Description

Control group: Oral Ibuprofen 10 mg / kg on day one and then two doses of 5mg / kg at 24 and 48 hours after administration of the dropper or through the NG tube and administered by a trained NICU nurse.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital

Full name of responsible person

Parvanae keshavarz

Street address

Shahid Beheshti Hospital, Motahari St., Felezi Bridge.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Haghjouye Javanmard Shaghayegh

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Amir Banazade

Position

Pediatric Resident

Latest degree

Medical doctor

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

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Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Latest degree

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amir_banazade@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

A portion of the data will be shared after the non-identifiable patients of study that contain the results of the treatment of Acetaminophen and also the demographic information of the patients.

When the data will become available and for how long

Three months after the publication of the results as an article.

To whom data/document is available

The data is available to researcher working in medical sciences.

Under which criteria data/document could be used

researcher who are doing in pediatric cardiology is available.

From where data/document is obtainable

To find out the data of this research, you can email Amir Binazadeh Resident of pediatric by e-mail.

What processes are involved for a request to access data/document

To access the research data after the request is sent, the researcher will be informed by email within 2 weeks for the delivery of the data to the applicant.

Comments