Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of oral Acetaminophen and intravenous Acetaminophen for closure of patent ductus arteriosus in preterm neonates admitted in neonatal intensive care unit of Akbar Abadi Hospital

Protocol summary

Study aim

Comparison of the efficacy of oral Acetaminophen and intravenous Acetaminophen for closure of patent ductus arteriosus in preterm neonates

Design

A simple randomization (according to table of random number), with a 2 parallel group, N=100 (each group n=50), Not blinded, Phase 3

Settings and conduct

This interventional study will conducted from May 2019 to July 2019. 100 preterm neonate with diagnosis of PDA admitted in NICU of Akbar Abadi Hospital Tehran were selected. Neonates are randomly assigned to two groups. In the first intervention group, oral Acetaminophen is given every 6 hours at a dose of 15 mg / kg for 3 days. In the second intervention group, IV Acetaminophen injected every 6 hours at a dose of 15 mg / kg for 3 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature neonate with diagnosis of PDA by pediatric cardiologist En Written parental consent is obtained Gestational age 26 to 37 weeks Exclusion criteria: No Parental consent. Any congenital heart disease that requires PDA to maintain blood flow (Based on patient records). Life threatening infections .(Based on patient records). Liver Diseases

Intervention groups

50 neonates in the first intervention group and 50 neonates in the second intervention group. In the first intervention group, oral Acetaminophen is given every 6 hours at a dose of 15 mg / kg for 3 days. In the second intervention group, IV Acetaminophen injected every 6 hours at a dose of 15 mg / kg for 3 days.

Main outcome variables

The closure of the ductus arteriosus (complete, incomplete, unchanged)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190505043478N1**
Registration date: **2019-05-10, 1398/02/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-10, 1398/02/20**
Update count: **0**

Registration date

2019-05-10, 1398/02/20

Registrant information

Name

Shadi Adib

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the efficacy of oral Acetaminophen and intravenous Acetaminophen for closure of patent ductus arteriosus in preterm neonates admitted in neonatal intensive care unit of Akbar Abadi Hospital

Public title
Comparison of the efficacy of oral Acetaminophen and intravenous Acetaminophen for closure of patent ductus arteriosus in preterm neonates

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Written parental consent is obtained Gestational age 26 to 37 weeks Diagnosis of ductus arteriosus based on echocardiographic evidence at 24 to 72 hours after birth
Exclusion criteria:
No Parental consent Any congenital heart disease with the need to PDA to keep blood flow constant (Based on patient records). Life threatening infections .(Based on patient records) Liver Disease

Age
From **1 day** old to **20 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
100 premature neonate assigned with simple randomization, according to table of random number and individual randomization unit. 50 neonates in the first intervention group and 50 neonates in the second intervention group were selected. In this study, do not allocation concealment.

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 Iran University of Medical Sciences
Street address
No. 193, Vahid dastgerdy Ave, Modares highway, Aliasghar Children Hospital
City
Tehran
Province
Tehran
Postal code
1919816766

Approval date
2019-04-16, 1398/01/27

Ethics committee reference number
IR.IUMS.FMD.REC.1398.026

Health conditions studied

1

Description of health condition studied
Patent ductus arteriosus (PDA)

ICD-10 code
Q25.0

ICD-10 code description
Patent ductus arteriosus

Primary outcomes

1

Description
PDA size

Timepoint
The neonates receives echocardiography before and after treatment.

Method of measurement
Patient PDA evaluated before and after treatment, based on severity of the disease, and findings of the echocardiography by pediatiric's cardiologist .

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Includes premature neonates with PDA diagnosis by pediatric cardiologist. In this group, samples (n=50) received oral Acetaminophen at a dose of 15mg / kg every 6 hours for 3 days.

Category
Treatment - Drugs

2

Description
Intervention group2: Includes premature neonates with PDA diagnosis by pediatric cardiologist. In this group,

samples (n=50) received IV Acetaminophen at a dose of 15mg / kg every 6 hours for 3 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi Hospital

Full name of responsible person

Shadi Adib

Street address

No. 193, Vahid dastgerdy Ave, Modares highway, Aliasghar Children Hospital

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shadiadib95@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakoti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Shadi Adib

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shadi Adib

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Semira Mehralizadeh

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable