

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 be conducted from May 2019 to July 2019. 100 preterm neonates 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 is 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. Enrolled with written parental consent. 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 is 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

adib.sh@iums.ac.ir

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 pediatric'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

Street address

Shahid Hemmat Highway, Iran 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

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