

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety and efficacy of venous Paracetamol with venous Ibuprofen in treatment of Patent ductus arteriosus (PDA) among premature Neonates Hospitalized in NICU, Zanzan Ayatollah Musavi Hospital in 2016- 2017

Protocol summary

Summary

All premature infants having age of 34 weeks or less with diagnosis PDA hospitalized in NICU of Ayatollah Musavi ,Zanzan and having moderate to severe PDA in two or three days after birth diagnosed through echocardiography together with hemodynamic disorder have been included in the current research. If suspected to have PDA , patients have been done echocardiography and graded in terms of PDA. 30 infants will be included in the research. Half of the patients will randomly receive Acetaminophen injection intravenous with dose of 15 mg/kg/QID till three days. The other half will receive Ibuprofen injection with dose of 10mg/kg/daily in the first day and 5 mg/kg/daily in the second and third day. Before starting research ,patient should pass Cr and BUN tests and platelet counting should not have symptoms of bleeding or Thrombocytopenia. Three days after Acetaminophen injection ,echocardiography should be repeated for the patients. In the case of not healing , they will receive Ibuprofen with dose of 10 mg/kg/daily in first day and 5 mg/kg/daily in the following second and third day. Patients will be examined when in hospital as well as when discharged. According to the findings ,the safety and effectiveness of Acetaminophen will be assessed in the form of semi-experimental pilot study. Strengths of the current study are as follows: 1. The effectiveness of Acetaminophen injection has not been studied compared to Ibuprofen in PDA treatment in Iran so far. 2. It seems that Acetaminophen does not have dangerous side effects of Ibuprofen. 3. If the effectiveness of the Acetaminophen is proved ,it is cheaper and more available.

General information

Acronym

PDA (Patent ductus arteriosus)

IRCT registration information

IRCT registration number: **IRCT2016081729404N1**

Registration date: **2017-05-09, 1396/02/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-09, 1396/02/19

Registrant information

Name

Nahid Jafari

Name of organization / entity

zanzan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Zanzan University of Medical Sciences

Expected recruitment start date

2017-03-16, 1395/12/26

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and efficacy of venous Paracetamol with venous Ibuprofen in treatment of Patent ductus arteriosus (PDA) among premature Neonates Hospitalized in NICU, Zanjan Ayatollah Musavi Hospital in 2016- 2017

Public title

Safety and efficacy of venous Paracetamol with venous Ibuprofen in treatment of Patent ductus arteriosus (PDA) among premature Neonates Hospitalized in NICU, Zanjan Ayatollah Musavi Hospital in 2016- 2017

Purpose

Treatment

Inclusion/Exclusion criteria

Neonate with 34 week age and less with PDA diagnosis by echocardiography.

Age

From **1 day** old to **3 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi blvd.

City

Zanjan

Postal code

4513956183

Approval date

2017-03-07, 1395/12/17

Ethics committee reference number

IR.ZUMS.REC.1395.312

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

PDA size before and after treatment measured with echocardiography by pediatric cardiologist.

Method of measurement

According to the disease severity and echocardiography results, Patient's PDA will be examined before and after treatment by pediatric cardiologists.

Secondary outcomes

empty

Intervention groups

1

Description

15 infants receive Ibuprofen with dose of 10 mg/kg/stat in the first day and 5 mg/kg/stat in the following second and third days.

Category

Treatment - Drugs

2

Description

15 infants receive Acetaminophen IV 15 mg/kg/ every six hours for three days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU, Musavi hospital

Full name of responsible person

Dr. Abolfazl Ebadi

Street address

Musavi hospital , Gavazang

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shogli

Street address

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City

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Grant name

بودجه معاونت تحقیقات و فن آوری دانشگاه

Grant code / Reference number

A - 11 - 1091 - 1

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Abolfazl Ebadi

Position

MD/ pediatric resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty