

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of prophylactic oral administration of acetaminophen on patent ductus arteriosus(PDA) closure in preterm neonate admitted in NICU section of Ali ibn Abitaleb Hospital in Zahedan in 2019-2020

Protocol summary

Study aim

Evaluation prophylactic oral acetaminophen administration on patent ductus arteriosus closure in preterm neonates based on gestational age and arterial diameter

Design

All preterm neonates with gestational age less than 32 weeks and weight less than 1500 g born in the NICU ward of Ali Ibn Abi Talib Hospital in Zahedan were randomly divided into the intervention group and received acetaminophen 15 mg / day in the intervention group. Each kilogram of body weight is given then on the fifth day of echocardiography will be performed.

Settings and conduct

The study will be carried out at Ali Ibn Abi Talib Hospital in Zahedan and the pediatric cardiologist who performs echocardiography is not aware of the neonatal segmentation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all preterm infants less than 32 weeks gestation and weight less than 1500 gr. Exclusion criteria: congenital heart disease; congenital major anomalies; non-steroidal anti-inflammatory drug use during pregnancy; persistent pulmonary hypertension; Apgar score less than 5; vomiting and hematemesis; G6PD deficiency; sepsis; intraventricular hemorrhage; urine output less than 1cc/kg/hr; creatinine greater than 1/8 mg/dl; platelet less than 50,000; necrotizing enterocolitis.

Intervention groups

The infants in the intervention group will be given an oral acetaminophen dose of 15 mg / kg from the first day of birth, then echocardiography will be performed on the fifth day of birth. In control group no intervention is performed.

Main outcome variables

Patent ductus arteriosus closure in preterm infants

General information

Reason for update

Acronym

PDA

IRCT registration information

IRCT registration number: **IRCT20200218046538N1**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

Registration date

2020-03-10, 1398/12/20

Registrant information

Name

Somayeh Baghiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4261 4781

Email address

som_baghiei1365@vatanmail.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of prophylactic oral administration of acetaminophen on patent ductus arteriosus(PDA) closure in preterm neonate admitted in NICU section of Ali ibn Abitaleb Hospital in Zahedan in 2019-2020

Public title
Effect of acetaminophen in patent ductus arteriosus

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All of preterm neonat Gestational $\leq$ less than 32 week
Weight less than 1500 gram
Exclusion criteria:
Congenital heart disease Major congenital anomaly Use of NSAID in pregnancy with mother Persistant pulmonary hypertention APGAR scor less than 5 Vomitting or hematemesis G6PD deficiency Sepsis Intra ventricular hemorrhage Urin out put less than 1 cc/kg/hr Cr more than 1/8 mg/dl Plt less than 50000 NEC

Age
From **1 day** old to **5 days** old

Gender
Both

Phase
2-3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible neonates are divided into two groups according to the random number table. Neonates with even numbers will be in the intervention group and neonates with odd numbers will be in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The cardiologist that performs Echocardiography He Does not know that which neonate Received Acetaminophen

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Sadra street, sadra 22
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9817957671
Approval date
2019-10-08, 1398/07/16
Ethics committee reference number
IR.ZAUMS.REC.1398.250

Health conditions studied

1

Description of health condition studied
Patent ductus arteriosus
ICD-10 code
Q20.8
ICD-10 code description
Other congenital malformations of cardiac chambers and connections

Primary outcomes

1

Description
Percentage of patent ductus arteriosus closure in preterm infants
Timepoint
Percentage of patent ductus arteriosus closure in preterm infants on fifth day of birth
Method of measurement
Echocardiography

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: premature babies with gestational age less than 32 weeks and weight less than 1500 g inter to study Then, from the first day of birth, oral acetaminophen will be given to the infant at 15 mg / kg every 6 hours, and on the fifth day the echocardiography will be performed.
Category
Treatment - Drugs

2

Description

Control group: no intervention is performed in this group and echocardiography will also be performed on the fifth day of birth without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abitaleb Hospital in Zahedan

Full name of responsible person

Somayeh Baghiee

Street address

Persian Gulf Boulevard

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817957671

Phone

+98 54 3329 5584

Email

Som_baghiee1365@vatanmail.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Noor Mohammad Bakhshany

Street address

Khalij Fars Boulevard

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Province

Sistan-va-Balouchestan

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Phone

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Email

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Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Somayeh Baghiee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Sadra street, Ziba shahr, Zahedan

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All patient information is available by patient code

When the data will become available and for how long

From the next 6 months

To whom data/document is available

All body

Under which criteria data/document could be used

Use data to conduct research that is relevant to the health of the community and individuals

From where data/document is obtainable

If you are approved by the university, you will be given a patient code if approved

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

If you are approved by the university, you will be given a patient code if approved

Comments