

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigation effect of oral acetaminophen and ibuprofen on Patent Ductus Arteriosus in preterm neonates

Protocol summary

Study aim

Effect of oral acetaminophen on the closure of Patent Ductus Arteriosus in preterm neonates

Design

The aim of this study is to compare the effect of oral acetaminophen and ibuprofen on closure of patent ductus arteriosus (PDA) in premature neonates. This is a randomized; without placebo-controlled; single center study. Premature neonates with 32 weeks or less with PDA will be enrolled in the study. Neonates who have congenital heart disease associated with arterial ducts will be excluded. Ninety premature neonates (32 weeks or less) with PDA at Tabriz Pediatric Children's Hospital, randomly (interlaced) will be divided into two parallel groups of intervention and control.

Settings and conduct

Ninety premature neonates (32 weeks or less) with patent ductus arteriosus at Tabriz Pediatric Children's Hospital, will be divided into two parallel groups. Patient informed consent will be obtained. The intervention group is premature neonates who will receive oral acetaminophen 10 mg/kg every six hours for three days. The control group is premature neonates who will receive oral ibuprofen 10 mg/kg at first day and 5 mg/kg at second and third day.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: 1. neonates 32 weeks or less 2. neonates with Patent Ductus Arteriosus Exclusion criteria are: 1. Congenital heart disease associated with Patent Ductus Arteriosus 2- neonates with syndromes 3- Increased pulmonary arterial pressure with right to left shunt 4. neonates whom have gastrointestinal intolerance

Intervention groups

Intervention group includes premature neonates who will receive oral acetaminophen 10 mg/kg every 6 hours for three days. Control group includes premature neonates who will receive oral ibuprofen 10 mg/kg on day 1 and 5 mg/kg on day 2 and day 3.

Main outcome variables

The initial outcome is the closure of Patent Ductus Arteriosus.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171227038102N1**

Registration date: **2018-07-03, 1397/04/12**

Registration timing: **retrospective**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

Registration date

2018-07-03, 1397/04/12

Registrant information

Name

Mahmoud Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

2014-06-26, 1393/04/05

Actual recruitment end date

2016-05-01, 1395/02/12
Trial completion date
empty

Scientific title
Investigation effect of oral acetaminophen and ibuprofen on Patent Ductus Arteriosus in preterm neonates

Public title
Investigation effect of oral paracetamol in closing PDA in premature neonates

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
preterm neonate Patent Ductus Arteriosus

Exclusion criteria:
Congenital heart disease afflicted by PDA Neonates with syndromes Increased pulmonary arterial pressure with left to right shunt Neonates who have digestive intolerance

Age
To 1 day old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: 90
Actual sample size reached: 90

Randomization (investigator's opinion)
Randomized

Randomization description
interlaced

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients randomly (interlaced) will be divided into two parallel groups of intervention and control and patients will not know about division of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz Children's Hospital, Sheshgelan, Tabriz, East Azerbaijan, Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5136735886

Approval date
2014-06-26, 1393/04/05

Ethics committee reference number
9346

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

Closure of Patent Ductus Arteriosus

Timepoint

At the beginning of the study

Method of measurement

By echocardiography

Secondary outcomes

1

Description

Side effects

Timepoint

The entire study period

Method of measurement

Serial clinical examinations

Intervention groups

1

Description

Intervention group: Premature infants who received oral acetaminophen 10 mg/kg every six hour for three days.

Category

Treatment - Drugs

2

Description

Control group: Premature infants who received oral ibuprofen 10 mg/kg on day 1 and 5 mg/kg on day 2 and

day 3.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Children's Hospital
Full name of responsible person
Mahmoud Samadi
Street address
Sheshgelan, Tabriz, East Azerbaijan, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Ata Mahmoudpour
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Mahmoud Samadi
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Nabaee

Position

Resident of Pediatrics

Latest degree

Medical doctor

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable