Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison between intravenous acetaminophen versus oral ibuprofen in preterm newborns with patent ductus arteriosus

Protocol summary

Study aim

Comparison of the effect of intravenous acetaminophen and oral ibuprofen on the closure of Patent Ductus Arteriosus in preterm infants

Design

Qualified subjects were nonrandomly divided into two groups A (injectable acetaminophen) and B (oral ibuprofen) for the presence or absence of contraindication for ibuprofen.The sample size in each group was 25 neonates. The study was performed as a non-randomized controlled clinical trial.

Settings and conduct

This study was performed prospectively.Inclusion criteria included preterm neonates admitted to the NICU of Imam Khomeini Hospital Complex with gestational ages and weights less than 37 weeks old and 2500 grams, respectively, who had hemodynamically significant PDA. Participants included 50 premature infants divided into two groups. Each participant was given a 3-days course of medicine (second course if necessary) and at the end of each course echocardiography was performed to determine response to treatment. The rate of ductal closure, need for second course of medical treatment, need for surgical treatment and side effects were recorded. Blinding method was that the participants, infants and the parents, had no information about type of medication.The statistician had also no information about type of medication.

Participants/Inclusion and exclusion criteria

All premature newborns with hemodinamically significant PDA in NICU department of Vali-Asr Hospital, Imam Khomeini Hospital Complex

Intervention groups

Group A: Intravenous acetaminophen Group B: Oral ibuprofen

Main outcome variables

closure of PDA, The need for drug re-treatment, The need for surgical treatment, Increased serum creatinine, Gastrointestinal bleeding, Necrotizing enterocolitis, Hyperbilirubinemia, Intraventricular Hemorrhage, Pulmonary Hemorrhage, Elevation of serum Aminotransferases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190206042639N1**
Registration date: **2019-09-24, 1398/07/02**
Registration timing: **retrospective**

Last update: **2019-09-24, 1398/07/02**
Update count: **0**

Registration date

2019-09-24, 1398/07/02

Registrant information

Name

Zeinab Harif nashtifani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8852 4107

Email address

hrf.z24@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2016-08-22, 1395/06/01

Actual recruitment end date

2018-01-10, 1396/10/20

Trial completion date

2018-01-20, 1396/10/30

Scientific title

The comparison between intravenous acetaminophen versus oral ibuprofen in preterm newborns with patent ductus arteriosus

Public title

The comparison between intravenous acetaminophen versus oral ibuprofen in preterm newborns with patent ductus arteriosus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants with hemodynamicaiy significant Patent Ductus Arteriosus Premature infant with a gestational age of less than 37 weeks and a birth weight of less than or equal to 2500 grams

Exclusion criteria:

Ductal dependent congenital Heart diseases Life threatening infections Syndromic manifestations Persistent Pulmonary Hypertention

Age

From **1 day** old to **15 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants (premature infants) have no information about prescribing drugs. The data analyzer has no information about type of Prescribing drugs. Safety Committee and Data Supervision has no information about type of Prescribing drugs.

Placebo

Not used

Assignment

Parallel

Other design features

Oral ibuprofen is a commonly used drug for treating PDA in premature infants in Iran.Contraindications for use in premature infants admitted to the NICU are abundant.The particular feature of our study was that we used intravenous acetaminophen (apotel) for patients who were contraindicated in taking ibuprofen and having a hemodinamicaly significant PDA. Therefore, patients who were normally deprived of treatment were treated with intravenous acetaminophen.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Blv, Qods Streat, Tehran Univercity of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-07-22, 1396/04/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.290

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 PDA in preterm infants

Timepoint

Echocardiography at 3 to 15 days of birth (before starting treatment), 4 days after starting treatment

Method of measurement

Echocardiographicaly

Secondary outcomes

1

Description

requires a second course of medical treatment

Timepoint

The day after the first course of medical treatment

Method of measurement

Ecocardiographicaly

2

Description
Need for surgical treatment
Timepoint
The day after the second course of medical treatment
Method of measurement
Ecocardiographicaly

3

Description
Increased serum creatinine
Timepoint
Any time after initiation of medical treatment
Method of measurement
Physical examination & laboratory tests

4

Description
Incidence of pulmonary hemorrhage
Timepoint
Any time after initiation of medical treatment
Method of measurement
Physical examination & CXR

5

Description
Incidence of intraventricular hemorrhage
Timepoint
Any time after initiation of medical treatment
Method of measurement
Physical examination & brain sonography

6

Description
Incidence of gastrointestinal bleeding
Timepoint
Any time after initiation of medical treatment
Method of measurement
Physical examination & laboratory tests

7

Description
Incidence of necrotizing enterocolitis
Timepoint
Any time after initiation of medical treatment
Method of measurement
Clinical and Paraclinical Examination

8

Description
Impaired liver function tests
Timepoint
Any time after initiation of medical treatment
Method of measurement
Clinical examination and laboratory tests

9

Description
Hyperbilirubinemia
Timepoint
Any time after initiation of medical treatment
Method of measurement
Clinical examination and laboratory tests

Intervention groups

1

Description
Intervention group: Oral ibuprofen with a dose of 10 mg per kg on the first day and then 5 mg per kilogram in the next two doses at intervals of 24 and 48 hours
Category
Treatment - Drugs

2

Description
Intervention group: Intravenous Acetaminophen With a dose of 10 mg per kg body weight every 6 hours up to a maximum of 60 mg per kg per day for 3 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex, Valiasr Hospital, NICU Department
Full name of responsible person
Zeinab Harif Nashtifani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr. Massoud Younesian

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Deputy Director of Research and Technology, Central Organization of Tehran University of Medical Sciences, Corner of Qods Street, Keshavarz Blvd
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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
Tehran University of Medical Sciences

Proportion provided by this source
50

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
Tehran University of Medical Sciences
Full name of responsible person
Zeinab Harif Nashtifani
Position
Pediatric Resident
Latest degree
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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
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

Study data include general data, study method, data analysis method, study results and general conclusions will be Published in validated journals and will be available to the researchers.

When the data will become available and for how long

In the next solar year

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

For clinical use, sharing among other researchers and benchmarking for similar cases

From where data/document is obtainable

Dr. Behzad Mohammadpour Ahrangani, End of keshavarz Blvd, Imam Khomeini Hospital, Valiasr Hospital, Children's Department, 00982161192361, postal code 1419733141

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

Applicants can access the study information by telephone or correspondence to the address of Dr. Behzad Mohammadpour Ahrandani.

Comments