Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of oral Acetaminophen with oral Ibuprofen in closure of Patent ductus arteriosus (PDA) in preterm neonate with gestational age less than 32 weeks

Protocol summary

Study aim

Comparison the effect of oral acetaminophen and oral ibuprofen in closing of Patent Ductus Arteriosus (PDA) in preterm neonate with gestational age less than 32 weeks in esfahan

Design

Two parallel randomized clinical trial and randomly divided into two groups of 20 patient and result will analysed double blinded.

Settings and conduct

This study was conducted at NICU of Al-Zahra and Shahid Beheshti hospitals of esfahan city and a neonatal nursing and cardiologist that was in charge of clinical follow-up was not aware of the type of drug used in the course of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: neonates with gestational age less than 32 weeks and a maximum age of 14 days and PDA has been confirmed by echocardiography. Exclusion criteria: neonates with chromosomal anomalies and congenital heart disease and clinical conditions Ibuprofen is contraindicated to start.

Intervention groups

In the first group, oral Acetaminophen is given at a dose of 15 mg / kg every 6 hours for 48 hours, given through the NG tube or through the dropper by a trained nurse. In the second group, oral Ibuprofen is given as 10 mg / kg on the first day and then 5 mg / kg at 24 and 48 hours, followed by a dropper or NG tube.

Main outcome variables

In this study, the effect of Acetaminophen on Patent ductus arteriosus, the duration of hospitalization and the complications of its use are investigated.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170801035441N1**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

Registration date

2018-07-09, 1397/04/18

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3335 5881

Email address

m.ghaderian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral Acetaminophen with oral Ibuprofen in closure of Patent ductus arteriosus (PDA) in

preterm neonate with gestational age less than 32 weeks

Public title
"Evaluation of the effect of oral acetaminophen on the treatment of neonatal PDAs"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All neonate with 32 weeks or less requiring PDA treatment for clinical conditions PDA is confirmed by echocardiography Age less than 14 days
Exclusion criteria:
Congenital heart disease Clinical and laboratory symptoms of sepsis Chromosomal or congenital abnormalities The presence of Ibuprofen is contraindicated
Age
From **1 day** old to **14 days** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, neonates in need of treatment will be divided into two groups using random numbers and each group will receive standard treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, nursing staff have no information about type of treatment. Only protocol 1 and 2 were recorded in follow-up treatment, so the next assessment was blinded by cardiology services, and it was only during the analysis of these protocols that the type of treatment was identified.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences and Health Services, hezar Jereyb St.
City
isfahan
Province
Isfehan
Postal code
۷۳۴۶۱-۸۱۷۴۶
Approval date
2018-03-07, 1396/12/16
Ethics committee reference number
396994

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
The closure rate of patent ductus arteriosus (PDA)
Timepoint
Echocardiography at the beginning of the study and then 48-72 hours after treatment
Method of measurement
Confirmed by echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For 48 hours, Drop of Acetaminophen made by the kimia gar Pharma Company at a dose of 15 mg / kg every 6 hours, given through the NG tube or through the dropper, by a nurse trained in neonates.
Category
Treatment - Drugs

2

Description
Control group: Oral Ibuprofen 10 mg / kg on day one and then two doses of 5mg / kg at 24 and 48 hours after administration of the dropper or through the NG tube and administered by a trained NICU nurse.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti hospital

Full name of responsible person
Parvanae keshavarz

Street address
Shahid Beheshti Hospital, Motahari St., Felezi Bridge.

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Phone
+98 31 3239 7001

Email
beheshti@mui.ac.ir

Web page address
http://beheshti.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Haghjouye Javanmard Shaghayegh

Street address
Hezar Jerib Blvd

City
Isfahan

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Phone
+98 31 3668 5149

Fax

Email
research@mui.ac.ir

Web page address
http://research.mui.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Amir Banazade

Position
Pediatric Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
No 42 ,Sajadie 2 Alley , Artesh Blvd

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3668 5321

Email
amir_banazade@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mehdi Ghaderian

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Cardiology

Street address
no 34, Alley 16,Chaharbaghe Paein st

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3335 5881

Fax

Email
m.ghaderian@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Amir Banazade

Position
Pediatric Resident

Latest degree
Medical doctor

Other areas of specialty/work
Pediatrics

Street address
No 42 ,Sajadie 2 Alley , Artesh Blvd

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3668 5321

Email
amir_banazade@yahoo.com

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
A portion of the data will be shared after the non-identifiable patients of study that contain the results of the treatment of Acetaminophen and also the demographic information of the patients.

When the data will become available and for how long
Three months after the publication of the results as an article.

To whom data/document is available
The data is available to researcher working in medical sciences.

Under which criteria data/document could be used
researcher who are doing in pediatric cardiology is available.

From where data/document is obtainable
To find out the data of this research, you can email Amir Binazadeh Resident of pediateric by e-mail.

What processes are involved for a request to access data/document
To access the research data after the request is sent, the researcher will be informed by email within 2 weeks for the delivery of the data to the applicant.

Comments