Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation Effectiveness of Ibuprofen and Acetaminophen in Closure of Patent Ductus Arteriosus

Protocol summary

Study aim

The aim is evaluation effectiveness of Ibuprofen and Acetaminophen in closure of Patent Ductus Arteriosus

Design

This assessment is a clinical trial in Phase 4, newborns diagnosed with Patent Ductus Arteriosus that have been verified by echocardiography, are considered as study group. In this study, 80 children who meet the criteria are selected. Patients are categorized based on blocked randomization method, 40 children in the ibuprofen group and 40 children in the acetaminophen group. Accordingly, at the beginning of the diagnosis and 3 days after the start of treatment, the condition of the Patent Ductus Arteriosus is evaluated by echocardiography.

Settings and conduct

This study was carried out as a clinical trial at the Pediatric Clinic of Amir Kabir Hospital in Arak, Also the study will also be single blinded in which patients will be blinded in study.

Participants/Inclusion and exclusion criteria

Infants less than 28 days of age referred to Amir Kabir Hospital, with Patent Ductus Arteriosus and without G6PD enzymatic defects, with physician approved and satisfactions of parents are enrolled to study. Also, children who are not willing to continue studying and also the neonates in case of congenital heart defects that Patent Ductus Arteriosus are life giving are excluded from the study.

Intervention groups

In the first group, the oral ibuprofen regimen (10 mg / kg / day) and in the second group oral acetaminophen regimen (7 mg / kg / day) are used, the duration of treatment for patients was three days from the start of treatment.

Main outcome variables

Patent Ductus Arteriosus Closure Status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130518013366N10**
Registration date: **2018-07-25, 1397/05/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-25, 1397/05/03**
Update count: **0**

Registration date

2018-07-25, 1397/05/03

Registrant information

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Name of organization / entity
Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation Effectiveness of Ibuprofen and Acetaminophen in Closure of Patent Ductus Arteriosus

Public title
Effect of Ibuprofen and Acetaminophen in Cardiac Vessels of Children
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infants less than 28 days old referring to Amir Kabir Hospital with Patent Ductus Arteriosus Parental consent for participation in the study No G6PD Enzymatic Deficiency
Exclusion criteria:
Dissatisfaction with using their information in the study Neonates with congenital heart defects that Patent Ductus Arteriosus were life giving, such as pulmonary artery atresia, congenital or chromosomal major abnormalities, the history of using non-steroidal anti-inflammatory drugs during pregnancy by mother, the presence of Hydrops Fetalis, and a continuous increase in Pulmonary Blood Pressure. Leaving the hospital with personal consent
Age
To **28 days** old
Gender
Both

Phase
4
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomization we will use the block method, Accordingly, the patients under study are divided into two groups. The allocation of patients in two groups was based on demographic characteristics and their matching. Based on this, after considering the patients' demographic data, patients were divided into two equal groups of patients, they enrolled in the study and performed desired intervention on them.
Blinding (investigator's opinion)
Single blinded
Blinding description
This means that patients in groups do not know the used drugs, and drugs has similar packaging.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Sardasht
City
Arak
Province
Markazi
Postal code
3848176941
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.ARAKMU.REC.1396.265

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
Patent Ductus Arteriosus Closure Status
Timepoint
Before intervention for diagnosis and within three days interval of starting the drug
Method of measurement
Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral ibuprofen ten milligrams per kilogram of body weight per day, for three days
Category
Treatment - Drugs

2

Description
Intervention group: Oral acetaminophen seven

milligrams per kilogram of body weight per day, for 3 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Maryam Beheshti Fard

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3819693345, Amir Kabir Hospital, Basij Square, Arak.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Yazdan Ghandi

Position

Assistant Professor of Pediatric cardiology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric cardiologist

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Person responsible for scientific inquiries

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Associate Professor of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable