

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 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

Name

Parsa Yousefi Chaijan

Name of organization / entity

Arak University of Medical Sciences

Country

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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

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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

Street address

3819693345, Amir Kabir Hospital, Basij Square, Arak.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

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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Full name of responsible person

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Position

Associate Professor of Pediatric Nephrology

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Nephrology

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Maryam Beheshty fard

Position

Pediatrician Student

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

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