

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Efficacy of Paracetamol versus Ibuprofen for the treatment of patent ductus arteriosus in neonates

Protocol summary

Study aim

Efficacy of Acetaminophen versus Ibuprofen in treatment of patent ductus arteriosus (PDA) in neonates

Design

This double blind randomized clinical trial is being conducted in a health center on 60 infants. The specialist and researcher will be blinded throughout the trial. Infants with hemodynamically significant PDA are randomly assigned to either intravenous acetaminophen or oral ibuprofen groups.

Settings and conduct

This double-blind study on the closure of PDA is conducted in the neonatal intensive care unit of Kashan Shahid Beheshti Hospital. The randomization was individual rather than cluster and individuals were assigned to groups based on random numbers generated by computer. In order to guarantee secure allocation concealment, a trained nurse will assign the neonates to different groups in a simple randomization process.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All neonates with post natal age more than 3days with hemodynamically significant PDA; Acceptance of informed consent by parents. Exclusion criteria: All congenital heart diseases other than PDA; Contraindication of using ibuprofen or acetaminophen; Persistence fetal circulation (PFC)

Intervention groups

In group A, intravenous Acetaminophen 15mg per kilogram per dose will be used every 6 hour for 3 days. In group B, oral Ibuprofen 10mg per kilogram per dose will be used on the first day and 5mg per kilogram per dose on 2nd and 3rd days. Finally the efficacy of Acetaminophen will be compared against Ibuprofen.

Main outcome variables

Closure of patent ductus arteriosus in neonates.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170910036112N2**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

Registration date

2018-03-04, 1396/12/13

Registrant information

Name

sima safaei

Name of organization / entity

kashan university

Country

Iran (Islamic Republic of)

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+98 21 2207 3673

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Science

Expected recruitment start date

2017-09-11, 1396/06/20

Expected recruitment end date

2018-03-11, 1396/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Paracetamol versus Ibuprofen for the treatment of patent ductus arteriosus in neonates

Public title

Efficacy of Paracetamol in treatment of patent ductus arteriosus in neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All neonates with post natal age more than 3 days with hemodynamically significant PDA; Acceptance of informed consent by parents.

Exclusion criteria:

All congenital heart diseases other than PDA
Contraindication of using ibuprofen or acetaminophen
Persistence fetal circulation (PFC)

Age

From **3 days** old to **7 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual randomization will be used and the allocation schedule will be planned using a computerized randomization. Infants with patent ductus arteriosus will be randomly assigned to either intravenous acetaminophen or oral ibuprofen. For blinding, a trained nurse with no clinical involvement in the trial, will assign the infants to the groups according to the random allocation sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, neonates with symptoms of patent ductus arteriosus (PDA) undergo echocardiography by a cardiologist who has no information on neonates' individual characteristics. Those neonates who meet the PDA diagnosis criteria and need treatment are assigned to different drug groups are unknown to the cardiologist. The diagnosed neonates are categorized to groups A and B according to the specific defined plans and receive treatment. The researcher is not aware of the type of treatment. Finally, echocardiography will be repeated for diagnosed neonates for the second time while the cardiologist is not still aware of the type of the treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

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Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2017-03-08, 1395/12/18

Ethics committee reference number

IR.KAUMS.REC.1395.164

Health conditions studied

1

Description of health condition studied

Patent ductus arteriosus in neonate

ICD-10 code

Q25.0

ICD-10 code description

Patent Ductus Arteriosus

Primary outcomes

1

Description

Closure of PDA in neonate

Timepoint

72 hours after birth and after 3 days of therapy initiation (therapy completion)

Method of measurement

Echocardiography

Secondary outcomes

1

Description

–

Timepoint

–

Method of measurement

–

Intervention groups

1

Description

Intervention group 2: Oral Ibuprofen 10mg/kg/dose for first day and 5mg/kg/dose for second and third day

Category

Treatment - Drugs

2

Description

Intervention group 1: Intra venous Paracetamol 15mg/kg/dose every 6hours for 3 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Ghotbe Ravandi Blvd, Kashan, Iran

Full name of responsible person

Sima Safaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan 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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Sima Safaei

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Web page address**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

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

Person responsible for updating data**Contact****Name of organization / entity**

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