

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Study the effect of acetaminophen prophylaxis on ductus arteriosus closure in premature infants under 31 weeks

Protocol summary

Study aim

The aim of this study is to investigate the effect of acetaminophen prophylaxis on ductus arteriosus closure in premature infants under 31 weeks.

Design

Randomized clinical trials with control group, community based and pragmatic with parallel groups, non blinded

Settings and conduct

In this study, 64 premature infants admitted to the neonatal intensive care unit of Shahrekord Hajar hospital were enrolled in the study, using convenience sampling method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants admitted to the neonatal intensive care unit, weight under 1500 grams and age under 31 weeks; In addition infants with congenital heart defects, congenital major abnormalities or chromosomal abnormalities, Apgar scores greater than 5 at five minutes after birth, symptomatic PDA require treatment with ibuprofen, vomiting or hematemesis in the first three days of birth, high levels of liver enzymes; infants with hydrops fetalis; infants whose mothers have a history of using nonsteroidal anti-inflammatory drugs during pregnancy; prevented from being enrolled in the study.

Intervention groups

Patients will be divided into two groups (intervention and control). The intervention group will receive acetaminophen prophylaxis (10 mg/ kg body weight every 6 hours for 5 days as drops). The control group will not receive any intervention. After 10 days, both groups will undergo echocardiography. In the case of ductus arteriosus, patients will receive the usual treatment (ibuprofen) and again after 1 month echocardiography will be done.

Main outcome variables

Ductus arteriosus condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190305042935N1**

Registration date: **2019-03-14, 1397/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-14, 1397/12/23**

Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Abdolrahim Kazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3334 9507

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-05-22, 1398/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of acetaminophen prophylaxis on ductus arteriosus closure in premature infants under 31 weeks

Public title
Effect of acetaminophen prophylaxis on ductus arteriosus closure in premature infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Premature infants admitted to the neonatal intensive care unit Weight under 1500 grams Age under 31 weeks
Exclusion criteria:
 Infants with congenital heart defects, congenital major abnormalities or chromosomal abnormalities Infants whose mothers have a history of using nonsteroidal anti-inflammatory drugs during pregnancy Infants with hydrops fetalis Infants with Apgar scores greater than 5 at five minutes after birth Infants with symptomatic PDA require treatment with ibuprofen Infants have vomiting or hematemesis in the first three days of birth Infants with high levels of liver enzymes

Age
To **210 days** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done by convenience method and numbers from 1 to 64 will be assigned to infants based on enrollment order. Infants will be randomly allocated to two intervention and control groups using Random Number Generation (RNG) software. Information such as sample size, study population and number of study groups will be recorded in the software. The software will generate two groups of random numbers for intervention (n: 32) and control (n: 32) groups, according to which allocation will be done.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrekord University of Medical Sciences

Street address

Research Deputy, Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

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Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Approval date

2018-06-24, 1397/04/03

Ethics committee reference number

IR.SKUMS.REC.1397.091

Health conditions studied

1

Description of health condition studied

Delayed closure of ductus arteriosus

ICD-10 code

P29.3

ICD-10 code description

Persistent fetal circulation

Primary outcomes

1

Description

Ductus arteriosus status

Timepoint

Ten and thirty days after intervention

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will receive acetaminophen prophylaxis 10 mg/ kg body weight, every 6 hours for 5 days as drops.

Category

Treatment - Drugs

2

Description

Control group: This group will not receive any medical treatment.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahrekord Hajar hospital

Full name of responsible person

Doctor Nabiollah Asadpour

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Seyed Kamal Solati

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Fax**Email**

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Web page address<https://research.skums.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Doctor Nabiollah Asadpour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

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Phone

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