

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of oral Ibuprofen in term Infants with Patent Dactus Arteriosus

Protocol summary

Study aim

Determination of the effect of oral Ibuprofen in term Infants with Patent Dactus Arteriosus (PDA)

Design

This study is a clinical trial with a control group, parallel groups, double-blinded and randomized.

Settings and conduct

This study is done in Imam Ali clinic in Shahrekord. 40 term infants randomly assign to two groups of 20 and Intervention is done . echocardiography is performed on the day of 7 after intervention, and neonates are evaluated for pda closure. infants assignment is done by the secretary and physician doing echocardiography is not aware of the allocation of infants to study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age more than 37 weeks. age between 5 and 30 days old. PDA size more than 1.5 mm detected by echocardiography. Exclusion criteria: having ductal dependent congenital heart disease, creatinine more than 88.5 micromol/l, platelet count less than 50000.

Intervention groups

Intervention group: receiving Ibuprofen, as an oral aqueous suspension (100 mg/5 ml; Alborz pharmaceutical) with a dose of 10 mg/kg at the beginning and four doses of 5 mg/kg with 24 hours intervals Control group: receiving no drug.

Main outcome variables

Closure of Patent dactus arteriosus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042618N1**

Registration date: **2019-02-15, 1397/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-15, 1397/11/26**

Update count: **0**

Registration date

2019-02-15, 1397/11/26

Registrant information

Name

najme bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 8235

Email address

st_bagherin@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-11, 1397/04/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of oral Ibuprofen in term Infants with Patent Dactus Arteriosus

Public title

The effects of Ibuprofen on term infants arterial duct

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age more than 37 weeks Age between 5 and 30 days old Patent dactus arteriosus size more than 1.5 mm detected by echocardiography

Exclusion criteria:
 Having ductal dependent congenital heart disease
 Creatinine more than 88.5 micromol/l Platelet count less than 50000

Age
 From **5 days** old to **30 days** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
 Target sample size: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple randomization, The assignment of infants to these two groups is done in such a way that the infants parents choose a card from 40 colored cards that are designed in two different colors and according to the chosen color the infant goes to one of the two groups (Each card belongs to one of the study cases.)

Blinding (investigator's opinion)
 Double blinded

Blinding description
 After conducting echocardiography and confirming the presence of Patent ductus arteriosus by the doctor, infant's parents go to the secretary and By choosing a card, they randomly go to one of the two groups of interventions. Then the secretary Based on the relevant group, gives the infant's parent ibuprofen susp and explains how and how much it is consumed or dose not give any drug .she records the required information in the list. Also in reoccurrence to examine the closure of the arterial duct, echo results recorded by the secretary in the previous checklist. So the doctor, who evaluates the ductus arteriosus closure does not know the allocation of newborns to study groups.

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

Vice chancellor for research, Building No. 2,
 University headquarters, Ayatollah Kashani Blvd

City
 Shahrekord

Province
 Chahar-Mahal-va-Bakhtiari

Postal code
 8815713492

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

Patent Dactus Arteriosus

ICD-10 code

Q25.0

ICD-10 code description

Patent ductus arteriosus

Primary outcomes

1

Description

Patent Dactus Arteriosus closure

Timepoint

Day one, Day 7 after intervention

Method of measurement

Eco cardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: reciving Ibuprofen, as an oral aqueous suspension (100 mg/5 ml; Alborz pharmaceutical) with a dose of 10 mg/kg at the beginning and four doses of 5 mg/kg with 24 hours intervals

Category

Treatment - Drugs

2

Description

Control group: reciving no drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Dr. Nabi Allah Asadpour

Street address

Imam Ali Clinic.,Shariati Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816788640

Phone

+98 38 3224 2696

Email

N.ASADPOUR@SKUMS.AC.IR

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Seyed Kamal Solati(Associate Professor of Psychology)

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3334 2414

Email

kamal_solati@yahoo.com

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

Dr. Nabi Allah Asadpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shahrekord University of Medical Sciences, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3224 8235

Email

n.asadpour@skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Nabi Allah Asadpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shahrekord University of Medical Sciences, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3227 4004

Email

N.asadpour@skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Nabi Allah Asadpour

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Shahrekord University of Medical Sciences, Building
No. 2, University headquarters, Ayatollah Kashani
Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3227 4004

Email

N.asadpour@skums.ac.ir

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

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete studies

From where data/document is obtainable

Hajar Hospital in Shahrekord

What processes are involved for a request to access data/document

after the investigation of resercher request and presentation of required documents will be accessible.

Comments