Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of high dose oral ibuprofen in treatment of patent ductus arteriosus in term neonate

Protocol summary

Summary

The goal of study is to determine the effect of high dose oral ibuprofen in patent with ductus arteriosus (PDA) in term neonate.The study population are neonates with gestational age 37 weeks or more and 3 to 30 days after birth. The inclusion criterion is patent ductus arteriosus, the exclusion criteria include: congenital heart disease (CHD) dependent to PDA, kidney disease, coagulating disorders and inability to oral feeding. Sample size is 33 neonates. All neonates receive oral ibuprofen (single dose 20 mg/kg in first day, 10 mg/kg in second day and 10 mg/kg in third day). Doppler Echocardiography is done one day before and one day after treatment. All neonates are monitored for the side effects of drug such as , gastrointestinal bleeding, impaired renal function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112220029N1**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name

Mehrdad Rezaei

Name of organization / entity

Shiraz University Of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose oral ibuprofen in treatment of patent ductus arteriosus in term neonate

Public title

Effect of ibuprofen in treatment of congenital heart disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age 37 weeks or more, age of after birth: 3 to 30 days, patent ductus arteriosus. exclusion criteria: congenital heart disease dependent to patent ductus arteriosus, unable to feeding, bleeding tendency disorder, oliguria, creatinin more than 1.8 mg/dl.

Age

From **3 days** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University Of Medical Sciences

Street address

Zand Street,Central Building of Shiraz University Of Medical Science

City

Shiraz

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

CT-P-91-6370

Health conditions studied

1

Description of health condition studied

Patent ductus arteriousus

ICD-10 code

Q25.0

ICD-10 code description

Patent ductus arteriousus

Primary outcomes

1

Description

closure of dutus arteriosus

Timepoint

one day before intervention and one day after end of intervention

Method of measurement

Doppler Echocardiography Vivid 3 ultrasound machine GE vingmed, Horten, Norwey

Secondary outcomes

1

Description

side effects like decrease urine output, gastrointestinal bleeding and discomfort, impaired renal function

Timepoint

one day before intervention, second day of intervention, one day after intervention

Method of measurement

clinical evaluation and check CBC, Creatinin , platelet, urine output

Intervention groups

1

Description

Administer oral ibuprofen(suspension 100 mg/5 ml from Hakim drug company) as 20 mg/kg in first day,10 mg/kg in second day and 10 mg/kg in third day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr. Mehrdad Rezaei

Street address

Zand street, Namazi Hospital, Neonatal Intensive Care Unit

City

Shiraz

2

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Dr. Mehrdad Rezaei

Street address

Chamran street, Hafez Hospital, Neonatal Intensive Care Unit

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research Of Shiraz University Of Medical Sciences

Full name of responsible person
Dr. Seyed Basir Hashemi

Street address
Zand Street, Central building of Shiraz University Of Medical Sciences

City
Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for Research Of Shiraz University Of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University Of Medical Science

Full name of responsible person
Dr.Mehrdad Rezaei

Position
Neonatology subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty