

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Studying the efficacy of synchronous consumption of Acetaminophen and Ibuprofen for closure of patent ductus arteriosus (PDA) in preterm neonates admitted in neonatal intensive care unit

Protocol summary

Study aim

Determining the effect of simultaneous use of acetaminophen and ibuprofen to open the arterial duct in preterm infants admitted to hospitals affiliated to Shiraz University of Medical Sciences

Design

clinical trial on 210 premature infants with PDA which need to be treated, with a control group, pragmatic, with 3 parallel groups, non blinded and simple Random assignment using a random number table.

Settings and conduct

This study was designed to evaluate the effect of different methods of medical treatment of premature infants admitted to the intensive care unit in Nemazee, Hafez and Hazrat Zeinab hospitals in Shiraz. for this purpose 210 premature infant were enrolled in 3 groups of 70.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- premature infants less than 37 weeks 2- premature infants with patent ductus arteriosus who require treatment exclusion criteria: 1 - NPO 2- massive bleeding from ETT or GI bleeding 3. Platelet count less than 50/000 per millimeter cubic meter 4. Urine output less than 1millilitr per kilogram per hour 5. Serum creatinine greater than 1.5miligram per decilitre 6. Intra-ventricular hemorrhage grade 3 and 4 7. Increase more than 2 times the hepatic enzymes (NL ALT: 6-50 and NL AST: 35-140) (10) 8-Major Congenital Anomalies 9-Congenital Heart Disease 10-Sepsis 11- Persistent Fetal Circulation

Intervention groups

The first group consists of 70 neonate treated with oral ibuprofen in 3 daily doses of 10, 5 and 5 mg per kg body weight per day. The second group consists of 70 premature infants who received an intravenous injection of 15 mg acetaminophen per kilogram of body weight every 6 hours for 3 days. The third group consists of 70

premature newborns who simultaneously receive oral ibuprofen and injectable acetaminophen at the same dose and duration as the other two groups.

Main outcome variables

closing or remaining PDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171116037503N2**

Registration date: **2018-10-30, 1397/08/08**

Registration timing: **retrospective**

Last update: **2018-10-30, 1397/08/08**

Update count: **0**

Registration date

2018-10-30, 1397/08/08

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4297

Email address

ooodir@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the efficacy of synchronous consumption of Acetaminophen and Ibuprofen for closure of patent ductus arteriosus (PDA) in preterm neonates admitted in neonatal intensive care unit

Public title
the effect of Acetaminophen and Ibuprofen for closure of patent ductus arteriosus (PDA)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
premature infants less than 37 weeks of gestational age
premature infants who require treatment for patent ductus arteriosus
Exclusion criteria:
1 . Prohibition of oral feeding 2.massive bleeding from ETT or GI bleeding 3. Platelet count less than 50/000 per mili cubic meter 4. Urine output less than 1mililitr per kilogram per hour 5. Serum creatinine greater than 1.5miligram per decilitre 6. Intra-ventricular hemorrhage grade 3 and 4 7. Increase more than 2 times the hepatic enzymes (NL ALT: 6-50 and NL AST: 35-140) 8-Major Congenital Anomalies 9-Congenital Heart Disease 10-Sepsis 11-Persistent Fetal Circulation

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

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **210**
Actual sample size reached: **149**

Randomization (investigator's opinion)
Randomized

Randomization description
These infants are divided into three groups based on the pattern determined by the simple randomization method and random number table

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 Shiraz University of Medical Sciences

Street address

Zand street, Nemazee hospital

City

Shiraz

Province

Fars

Postal code

7193711351

Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

IR.SUMS.MED.REC.1396.72

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

Closing patent ductus arteriosus

Timepoint

before intervention and on day four after end of treatment

Method of measurement

Ecocardiography

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group consists of 70 premature neonate who received an intravenous injection of 15 mg acetaminophen per kg of body weight every 6 hours for three days.

Category

Treatment - Drugs

2

Description

The second intervention group consists of 70 premature newborns who simultaneously received oral ibuprofen on the first, second and third days, respectively, 10mg, 5mg and 5 mg per kg body weight per day and intravenous injection of 15 mg acetaminophen per kg of body weight every 6 hours for three days.

Category

Treatment - Drugs

3

Description

Includes 70 premature infants treated with oral ibuprofen for three consecutive days with doses of 10 mg, 5 mg and 5 mg per kg body weight per day, respectively.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nemazee Hospital

Full name of responsible person

Roya Oboodi

Street address

Zand street, Nemazee Hospital

City

Shiraz

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7193711351

Phone

+98 71 3647 4298

Email

ooodir@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Zand street, Shiraz Medical University Of Science

City

Shiraz

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Postal code

713451978

Phone

+98 71 3235 7282

Email

vcrdep@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

50

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

Shiraz University of Medical Sciences

Full name of responsible person

Roya Oboodi

Position

Associate professor of Neonatology

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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ooodir@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Khadije sadat Najib

Position

Assistant Professor of Neonates

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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nzahrasan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Roya Oboodi

Position

Assistant Professor of Neonates

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

Participants data file: information and research data

Ethic form: complete the ethic form by parents

When the data will become available and for how long

The start of the access period 6 month after the registration of the results.

To whom data/document is available

participants data file: researchers and patient ethic form: patients

Under which criteria data/document could be used

awareness of the study results

From where data/document is obtainable

pediatric ward Shiraz university of medical science

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

with the letter of introduction from the university 's vice chancellor to the children's department

Comments