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 milimeter 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) (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 intravenus 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

oboodir@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

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7193711351

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+98 71 3647 4298

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oboodir@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

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713451978

Phone
+98 71 3235 7282

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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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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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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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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