

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical trial of the effect of intravenous acetaminophen in patent ductus arteriosus prophylaxis of preterm infants with gestational age less than 32 weeks

Protocol summary

Study aim

Determination of the effect of intravenous acetaminophen on patent ductus arteriosus prophylaxis of preterm infants with gestational age less than 32 weeks

Design

Clinical trial with control group, with parallel groups, single-blinded, and randomized

Settings and conduct

On the first to third day of birth, the first echocardiography will be performed. Then, between day 3 to 5, the echocardiography will be repeated, and condition of ductus arteriosus will be recorded.

Participants/Inclusion and exclusion criteria

Preterm infants with gestational age less than 32 weeks who are admitted to the NICU ward of Bouali Hospital of Sari for less than 72 hours

Intervention groups

In the intervention group, intravenous acetaminophen manufactured by Iran Exir Company with a dose of 10 mg/kg is injected each 12 hours for two days and in the control group, normal saline made by Daroopaksh Company at a dose of 10 mg/kg is injected each 12 hours for two days as a placebo

Main outcome variables

One to three days after the intervention, ALT, AST, BUN, Cr, PT and INR tests will be performed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111011007763N2**

Registration date: **2018-03-03, 1396/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-03, 1396/12/12**

Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Vajihe Ghaffari

Name of organization / entity

mazandaran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 2334

Email address

vgghaffari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-05-24, 1397/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of intravenous acetaminophen in patent ductus arteriosus prophylaxis of preterm infants with gestational age less than 32 weeks

Public title

Effect of intravenous acetaminophen in prevention of

patent ductus arteriosus in preterm infants

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Preterm infants with gestational age <32 weeks
Exclusion criteria:
Lethal anomalies Congenital heart diseases Existing
patent ductus arteriosus

Age
To 3 days old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method is simple and by using table of random numbers

Blinding (investigator's opinion)
Single blinded

Blinding description
The cardiologist will be unaware of the assignment of the studied groups

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem Square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2016-10-30, 1395/08/09
Ethics committee reference number
IR.MAZUMS.REC.95-2336

Health conditions studied

1

Description of health condition studied

Persistent ductus arteriosus

ICD-10 code

Q25

ICD-10 code description

Patent ductus arteriosus

Primary outcomes

1

Description

Opening of patent ductus arteriosus

Timepoint

1 to 3 days after birth

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Intraventricular hemorrhage

Timepoint

1 to 3 days after birth

Method of measurement

Brain sonography

2

Description

Gastrointestinal bleeding

Timepoint

1 week

Method of measurement

Clinical examination

3

Description

Necrotizing enterocolitis

Timepoint

1 week

Method of measurement

Clinical examination and stool exam

4

Description

Oliguria

Timepoint

1 week

Method of measurement

Measurement of urine volume

5

Description

Pulmonary hemorrhage

Timepoint

1 week

Method of measurement

Clinical examination

Intervention groups

1

Description

In the intervention group, an intravenous acetaminophen made by Iran Exir Company at a dose of 10 mg/kg is injected each 12 hours

Category

Prevention

2

Description

In the control group, for two days, intravenous normal saline made by Daroopaksh Company at a dose of 10 mg/kg is injected each 12 hours as placebo.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Hospital of Sari

Full name of responsible person

Vajiheh Ghaffari

Street address

Bouali Hospital, Pasdaran Boulevard, Sari, Iran

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vghaffari@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Bouali hospital, Pasdaran Blv, Sari, Iran

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Phone

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Email

msaeedi@mazums.ac.ir

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, Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Nasim Meh

Position

Pediatrics Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

Bouali hospital, Pasdaran Blv, Sari, Iran

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Nasim Meh

Position

Pediatric Resident

Latest degree

Medical doctor

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

Yes - There is 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

Yes - There is 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

Part of the data is available

When the data will become available and for how long

Starting from January 2020

To whom data/document is available

All people

Under which criteria data/document could be used

Nothing

From where data/document is obtainable

Call Dr. Nasim Meh, +989123585393 Email: nasimmeh62@yahoo.com

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

After a call, information is sent within a few days

Comments

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Nasim Meh

Position

Pediatric Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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City

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