

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the therapeutic and Safety effect of oral and rectal acetaminophen for treatment and safety on the closure of ductus arteriosus in preterm neonates under 35 weeks and 6 days gestational old.

Protocol summary

Study aim

Comparison of the therapeutic and Safety effect of oral and rectal acetaminophen for treatment and safety on the closure of ductus arteriosus in preterm neonates under 35 weeks and 6 days gestational old.

Design

This study is a one-blinded clinical trial. The study population will be included all preterm neonates admitted to Mohammad Kermanshahi and Imam Reza Hospital of Kermanshah city. 40 eligible preterm neonates will be selected conveniently and randomly assigned to two intervention groups.

Settings and conduct

This study that will be conducted in Mohammad Kermanshahi and Imam Reza Hospital of Kermanshah city is one-blinded one. In this way that the researcher will be kept blind to the study groups, the dosage of the drug and the manufacturer of the medicine

Participants/Inclusion and exclusion criteria

Inclusion criteria: Preterm neonates under 35 weeks and 6 days gestational old; Age after birth be over 72 hours and less than 14 days; Neonates with hemodynamic disorders caused by PDA Exclusion criteria: Respiratory rate more than 80 per minute; Signs of renal failure and oliguria; Creatinine clearance less than 10%

Intervention groups

In the first intervention group, the treatment will begin with the administration of oral acetaminophen with a dose of 25 mg/kg body weight, then, will be administrated 15 mg per kg body weight every 8 hours for 3 days for babies over 1000 grams. In the second intervention group, the treatment will begin with the administration of rectal acetaminophen with a dose of 25 mg/kg body weight, then, will be administrated 15 mg per kg body weight every 8 hours for 3 days for babies over 1000 grams.

Main outcome variables

closure of ductus arteriosus in preterm neonates

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N118**

Registration date: **2019-04-11, 1398/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-11, 1398/01/22**

Update count: **0**

Registration date

2019-04-11, 1398/01/22

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-16, 1397/12/25

Expected recruitment end date

2019-12-16, 1398/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic and Safety effect of oral and rectal acetaminophen for treatment and safety on the closure of ductus arteriosus in preterm neonates under 35 weeks and 6 days gestational old.

Public title

Comparison of the effect of oral and rectal acetaminophen on the closure of ductus arteriosus in preterm neonates under 35 weeks and 6 days gestational old.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Preterm neonates under 35 weeks and 6 days gestational old. Age after birth be over 72 hours and less than 14 days Neonates with hemodynamic disorders caused by PDA

Exclusion criteria:

Respiratory rate more than 80 per minute Signs of renal failure and oliguria Creatinine clearance less than 10%

Age

From **3 days** old to **14 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, Clinical care will be kept blind to study groups, the dosage of the drug and manufacturer of the drug. In this way, the clinicians are unaware of participants coding and the dose of the drug that groups will receive.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

ir.kums.rec.1397.1035

Health conditions studied**1****Description of health condition studied**

preterm neonates

ICD-10 code

P07.3

ICD-10 code description

Other preterm neonates

Primary outcomes**1****Description**

the closure of ductus arteriosus

Timepoint

The beginning and end of the study

Method of measurement

With echocardiography device

Secondary outcomes

empty

Intervention groups**1****Description**

In the first intervention group, the treatment will begin with the administration of oral acetaminophen with a dose of 25 mg/kg body weight, then, will be administrated 15 mg per kg body weight every 8 hours for 3 days for babies over 1000 grams.

Category

Treatment - Drugs

2

Description

In the second intervention group, the treatment will begin with the administration of rectal acetaminophen with a dose of 25 mg/kg body weight, then, will be administrated 15 mg per kg body weight every 8 hours for 3 days for babies over 1000 grams.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

hashem Gholami

Street address

Crossroads of Shirkhorshid

City

Kermanshah

Province

Kermanshah

Postal code

6713733135

Phone

+98 83 3721 8202

Email

gholami3280@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

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Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Hashem Gholami

Position

Resident of children

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mazyar Vakili Amini

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Hashem Gholami

Position

Resident of children

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

Street address

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Email

gholami3280@gmail.com

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

Undecided - It is not yet known if there will be 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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments