

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

On the efficiency of oral acetaminophen on artery closure among premature infants hospitalized in ICU

Protocol summary

Summary

The present study aims to investigate the effect of taking oral acetaminophen on closure of open arteries among immature infants hospitalized in ICU. It is a not blind clinical trial. 66 preterm infants in their pregnancy age of 34 weeks or less, who were hospitalized in Imam Reza hospital and did not respond to the prescription of oral ibuprofen twice a day, were selected and were treated by oral acetaminophen, liquid drop by Behas company, on dosage of 15 mg/kg every 6 hours during three days. Infants being treated by acetaminophen are checked for hypothermia immediately after taking the drug and every 30 minutes till an hour after the treatment. Samples were examined at the beginning and three days after the intervention to check their arteries. Inclusion: infants with contraindication using ibuprofen (oliguria: output less than 1cc/kg/hr. platelets less than 50000. Hyperbilirubinemia with the need to jaundice. Necrotizing enterocolitis perforation of the gastrointestinal tract); infants who were not treated through taking oral ibuprofen twice a day; infants with PDA determined by echocardiography. Exclusion: Congenital heart disease with the need to PDA to keep blood flow constant; life threatening infection; Intraventricular hemorrhage at 3 and 4 grades.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122714333N26**
Registration date: **2015-01-27, 1393/11/07**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-27, 1393/11/07

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

kermanshah university of medical sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2015-01-05, 1393/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

On the efficiency of oral acetaminophen on artery closure among premature infants hospitalized in ICU

Public title

On the efficiency of oral acetaminophen on artery closure among premature infants hospitalized in ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: infants with contraindication using ibuprofen (oliguria: output less than 1cc/kg/hr. platelets less than 50000. Hyperbilirubinemia with the need to jaundice. Necrotizing enterocolitis perforation of the

gastrointestinal tract); infants who were not treated through taking oral ibuprophen twice a day; infants with PDA determined by echocardiography. Exclusion: Congenital heart disease with the need to PDA to keep blood flow constant; life threatening infection; Intraventricular hemorrhage at 3 and 4 grades.

Age

From **8 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

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**

Kermanshah University of Medical Sciences

Street address

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

City

Kermanshah

Postal code**Approval date**

2014-11-11, 1393/08/20

Ethics committee reference number

420/7/35219/پ

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**

Patent or closure of Ductus Arteriosus

Timepoint

By a doctor

Method of measurement

At the beginning of the intervention and three after that

Secondary outcomes

empty

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

Experiment group included infants who were not treated through taking oral ibuprophen twice a day and were checked to be treated through taking oral acetaminophen with dose of 15 mg/kg every 6 hours for three days. Infants being treated by acetaminophen are checked for hypothermia immediately after taking the drug and every 30 minutes till an hour after the treatment

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neonatal intensive care unit, Emamreza hospital

Full name of responsible person

Dr. Raheleh Nemati

Street address

Emamreza hospital, Parastar boulevard

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Korosh Hamzehee

Street address

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

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Kermanshah

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

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Homa Babaei

Position

Neonatologist

Other areas of specialty/work

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Fax

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HOMA_BABAEI@KUMS.AC.IR

Web page address

Person responsible for updating data

Contact

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