# 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 ibuprophen 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 ibuprophen (oliguria: output less than 1cc/kg/hr. plackets 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.

## 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**

+98 83 1821 4653

**Email address**

fforoughi@kums.ac.ir

**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 ibuprophen (oliguria: output less than 1cc/kg/hr. plackets 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**
Koroush Hamzehee

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

**City**
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**
**Street address**
Emamreza hospital, Parastar boulevard
**City**
Kermanshah
**Postal code**
**Phone**
+98 83 3427 6300
**Fax**
**Email**
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*