

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus (PDA) in kosar Hospital-Iran

#### Protocol summary

##### Summary

**OBJECTIVE:** Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus (PDA). **Type of Study:** Double Blinded Clinical Trial with Randomized Controls. **Methodology & Research Design:** A. **Study Sample:** Premature infants with patent ductus arteriosus (PDA) (borned in Kosar Hospital-Iran). **o Inclusion Criteria:** Gestational age less than or equal to 34 weeks; Birth elapsed time less than or equal to 14 days; PDA diagnosis based on echocardiography findings. **o Exclusion Criteria:** Any type of congenital heart disease is to keep the blood flow needed PDA; Life-threatening infections; Grade 3-4 intraventricular hemorrhage (within recent 24 hours); Urinary output less than 1mg/kg/h in last 8 hours; Serum creatinine level higher than 88 µmol/L; platelet counts less than 109×50 per liter; Hyperbilirubinemia requiring blood transfusions; Active necrotizing enterocolitis or bowel perforation; Liver dysfunction; Gastrointestinal bleeding; Retinopathy; Bronchopulmonary dysplasia; Lack of parental consent. **o Sample Size:** At least 53 patients per group. **B. Investigated intervention/s:** The first group of patients treated with ibuprofen at a dose of 10 mg/kg/stat and then 5 mg/kg/12h to two doses, and the second group of patients treated with acetaminophen for two days at a dose of 15 mg/kg/6h (8 doses). **C. Intervention time:** The first 14 days of life. **D. The primary outcome or consequences of the study:** Echocardiographic findings indicate that closure of PDA.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120425357N1**

Registration date: **2015-12-20, 1394/09/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-12-20, 1394/09/29

##### Registrant information

###### Name

Tahereh Jangjoo Pirbazari

###### Name of organization / entity

Qazvin University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3333 4808

###### Email address

t.jangjoo@qums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2015-12-07, 1394/09/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus (PDA) in kosar Hospital-Iran

##### Public title

Comparison of oral ibuprofen versus acetaminophen in premature infants with patent ductus arteriosus

##### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion Criteria: Gestational age less than or equal to 34 weeks; Birth elapsed time less than or equal to 14 days; PDA diagnosis based on echocardiography findings.

Exclusion Criteria: Any type of congenital heart disease is to keep the blood flow needed PDA; Life-threatening infections; Grade 3-4 intraventricular hemorrhage (within recent 24 hours); Urinary output less than 1mg/kg/h in last 8 hours; Serum creatinine level higher than 88 µmol/L; platelet counts less than 109×50 per liter; Hyperbilirubinemia requiring blood transfusions; Active necrotizing enterocolitis or bowel perforation; Liver dysfunction; Gastrointestinal bleeding; Retinopathy; Bronchopulmonary dysplasia; Lack of parental consent.

### **Age**

From **1 day** old to **14 days** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **106**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **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**

Qazvin University of Medical Sciences - Children's Hospital in Qods

##### **Street address**

Qods Square

##### **City**

Qazvin

##### **Postal code**

#### **Approval date**

2014-12-31, 1393/10/10

#### **Ethics committee reference number**

20/9885/3

## **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**

heart murmur

#### **Timepoint**

Before intervention - three days after the intervention.

#### **Method of measurement**

Auscultation - Echocardiography

## **Secondary outcomes**

### **1**

#### **Description**

Bleeding Including the gastrointestinal tract, urinary tract and respiratory tract

#### **Timepoint**

During the intervention

#### **Method of measurement**

Clinical observation and tests such as analysis of urine and faeces

## **Intervention groups**

### **1**

#### **Description**

The first group of patients treated with ibuprofen at a dose of 10 mg/kg/stat and then 5 mg/kg/12h to two doses.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

The second group of patients treated with acetaminophen for two days at a dose of 15 mg/kg/6h (8 doses).

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Kosar Hospital Qazvin

##### **Full name of responsible person**

Tahereh Jangjoo Pirbazri

**Street address**

Vali Asr intersection - Taleghani Avenue

**City**

Qazvin

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

Qazvin University of Medical Sciences

**Full name of responsible person**

Abolfazi Mahyar

**Street address**

Qazvin -Street Shahid Bahonar

**City**

Qazvin

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qazvin 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****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Tahereh Jangjoo Pirbazari

**Position**

Resident of Pediatrics/Resident of Pediatrics

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esmail.jangjoo@gmail.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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esmail.jangjoo@gmail.com**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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esmail.jangjoo@gmail.com**Web page address****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*