

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Investigation of efficacy rate of prophylactic treatment with oral paracetamol for closure of patent ductus arteriosus in preterm infants admitted in neonatal intensive care unit

#### Protocol summary

##### Summary

The aim of the study is investigating the efficacy rate of prophylactic treatment with oral paracetamol for closure of patent ductus arteriosus in preterm infants. Inclusion criteria is premature neonates born at or before 32 weeks of gestation with birth weight less than or equal to 1500 grams and exclusion criteria is congenital major anomalies or chromosomal abnormalities. This interventional study will performed in premature newborns who admitted in neonatal intensive care unit of Vali-e-Asr Hospital in 2012-2013. Since thus far no studies have been conducted about the efficacy of acetaminophen for closure of patent ductus arteriosus, so 30 subjects are evaluated in this study. Subjects are randomly divided into 2 groups at beginning of admission. For the first group during first 24 hours after birth 15mg/kg oral acetaminophen will administrated every 6 hours for 48 hours. Echocardiography will performed for them during 24-36 hours after the last dose of acetaminophen by a pediatric cardiologist to evaluating of ductus arteriosus. Echocardiography of newborns in second group will also performed during 4-5 days old without any intervention by the same specialist to evaluate ductus arteriosus.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014090519050N1**  
Registration date: **2015-02-02, 1393/11/13**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-02-02, 1393/11/13

#### Registrant information

##### Name

Mohammad Reza Zarkesh

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8889 7764

##### Email address

zarkesh@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for research of Tehran university of medical sciences

#### Expected recruitment start date

2012-03-20, 1391/01/01

#### Expected recruitment end date

2013-03-20, 1391/12/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigation of efficacy rate of prophylactic treatment with oral paracetamol for closure of patent ductus arteriosus in preterm infants admitted in neonatal intensive care unit

#### Public title

The efficacy of prophylactic treatment with oral acetaminophen for closure of patent ductus arteriosus in preterm infants

#### Purpose

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Premature neonates born at or before 32 weeks of gestation with birth weight less than or equal to 1500 grams admitted in neonatal intensive care unit of Vali-e-Asr Hospital in 2012; parental consent for participating in this study. Exclusion criteria: Newborns with congenital heart defects that patency of ductus arteriosus is vital for them such as pulmonary atresia; congenital major anomalies or chromosomal abnormalities; maternal consumption of none steroidal anti-inflammatory drugs during pregnancy; newborns with hydrops fetalis or persistent pulmonary hypertension of the newborn; apgar score less than 5 at fifth minute after birth; appearance of patent of ductus arteriosus symptoms and requirement for treatment with Ibuprofen at any time; having vomiting or hematemesis during first 3 days after birth; neonates with glucose-6-phosphate dehydrogenase deficiency based on blood exam at beginning of neonatal admission

### **Age**

To 6 days old

### **Gender**

Both

### **Phase**

N/A

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

No information

### **Sample size**

Target sample size: 30

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

Randomized

### **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**

The Ethical Committee of Tehran University of Medical Science

##### **Street address**

The Ethical Committee of Tehran University of Medical Science, Vice Chancellor for research, 6th Floor, Tehran University of Medical Sciences, Corner of Ghodss Street, Keshavarz Blvd.

##### **City**

Tehran

##### **Postal code**

### **Approval date**

2013-08-04, 1392/05/13

### **Ethics committee reference number**

905/130/92/3

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

patent ductus arteriosus

#### **ICD-10 code**

Q25.0

#### **ICD-10 code description**

Congenital malformations of great arteries

## **Primary outcomes**

### **1**

#### **Description**

Left Atrial to Aortic Ratio

#### **Timepoint**

4-5 day of life

#### **Method of measurement**

Echocardiography

### **2**

#### **Description**

Internal Ductal Diameter

#### **Timepoint**

4-5 day of life

#### **Method of measurement**

Echocardiography

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Administration of 15mg/kg oral acetaminophen every 6 hours for 48 hours during first 24 hours after birth

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: No intervention

#### **Category**

N/A

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Imam Khomeini Hospital Complex, Vali-Asr Hospital

**Full name of responsible person**

Dr.Mohamad Reza Zarkesh

**Street address**

Imam Khomeini Hospital Complex, Vali-Asr Hospital,  
Keshavarz Blvd.

**City**

Tehran

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Tehran University of  
Medical Sciences

**Full name of responsible person**

Dr. Masud Yunesian

**Street address**

Vice Chancellor for research, 6th Floor, Tehran  
University of Medical Sciences, Corner of Ghodss  
Street, Keshavarz Blvd.

**City**

Tehran

**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 of Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Mohamad Reza Zarkesh

**Position**

Neonatologist

**Other areas of specialty/work****Street address**

Tehran Women Hospital, North Nejatollahi Street,  
Karim Khan Zand Avenue

**City**

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**Postal code****Phone**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad reza zarkesh

**Position**

Neonatologist

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Zarkesh

**Position**

Assistant professor, Head manager of NICU

**Other areas of specialty/work****Street address**

Tehran Women Hospital, North Nejatollahi Street,  
Karim Khan Zand Avenue

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**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*