

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Assess the efficacy of preventive paracetamol dosage for the closure of patent ductus arteriosus (PDA) in preterm infants.

#### Protocol summary

##### Summary

Purpose: efficacy assessment of preventive paracetamol dosage for the closure of patent ductus arteriosus (PDA) in preterm infants. Design: The study is a randomized double-blind clinical trial which will perform on 160 preterm neonates with less than 34 weeks gestational age in NICU ward. Neonates randomly divided into the test and control groups. Method: Neonates in test group, will receive intravenous paracetamol with the loading dose of 20 mg/kg and maintenance dose of 7.5 mg/kg every 6 hours during first three postnatal days and the neonates in control group will not receive any drugs. Study participants: all of preterm neonates which will hospitalize between November 2015 and November 2016 in in NICU ward of Afzalipour hospital of Kerman city, Iran. Intervention: intravenous paracetamol with the loading dose of 20 mg/kg and maintenance dose of 7.5 mg/kg every 6 hours during first three postnatal days. Outcome: frequency of closing in patent ductus arteriosus after study intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012718994N2**  
Registration date: **2017-03-08, 1395/12/18**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-03-08, 1395/12/18

##### Registrant information

###### Name

Amir Bahrami-Ahmadi

###### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

chancellor for research, Kerman University of Medical Sciences

##### Expected recruitment start date

2015-11-22, 1394/09/01

##### Expected recruitment end date

2016-06-22, 1395/04/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assess the efficacy of preventive paracetamol dosage for the closure of patent ductus arteriosus (PDA) in preterm infants.

##### Public title

Assess the efficacy of paracetamol for the closure of patent ductus arteriosus (PDA) in preterm infants.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Less than 32 week gestational age  
Exclusion Criteria: Pulmonary artery atresia; aorta coarctation; major maternal anomalies; Hydrops fetalis; pulmonary hypertension; mortality of infants during prophylactic therapy

##### Age

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomization in this study will perform by Balance-Block randomization method

**Secondary Ids**

empty

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

Ethics committee of research of Kerman university of medical sciences

**Street address**

Ebnesima Street- Jahad Blv-Tahmasb Abad

**City**

Kerman

**Postal code****Approval date**

2017-02-13, 1395/11/25

**Ethics committee reference number**

IR.KMU.REC.1395.841

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

Patent ductus arteriosus (PDA)

**ICD-10 code**

Q 25.0

**ICD-10 code description**

Persistent ductus arteriosus

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

Ventilator usage time

**Timepoint**

Three days after Intervention

**Method of measurement**

according NICU report

**2****Description**

Hospitalization time

**Timepoint**

Three days after Intervention

**Method of measurement**

according NICU report

**3****Description**

Mortality rate of infants

**Timepoint**

Three days after Intervention

**Method of measurement**

according NICU report

**Secondary outcomes**

empty

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

Intervention group: more than routine NICU management, Paracetamol with initial dosage 20 mg/kg and maintenance dosage: 7.5 mg/kg/dose every six hours for three days.

**Category**

Prevention

**2****Description**

Control group: only routine NICU management

**Category**

Prevention

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

Afzalipour Hospital

**Full name of responsible person**

Farhad Azizzadeh

**Street address**

کرمان ، بزرگراه امام ، پردیسه افضلي پور ، بیمارستان افضلي پور

**City**

Kerman

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice-Chancellor of Kerman University of Medical Sciences

**Full name of responsible person**

Dr Abbas Pardakhti

**Street address**

Vice-Chancellor of Kerman university of medical sciences, Ebn-e-sina Street, Tahmasb Abad Crossroad- Kerman-Iran

**City**

Kerman

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

Yes

**Title of funding source**

Vice-Chancellor of Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Farhad Azizzadeh

**Position**

Pediatric specialist

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

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## Person responsible for scientific

## inquiries

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**Full name of responsible person**

Dr MOhammad Hossein Torabinejad

**Position**

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## Person responsible for updating data

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**Full name of responsible person**

Dr Amir Bahrami-Ahmadi

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## 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*