

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### A comparative study of the effectiveness of injectable Acetaminophen in closing Patent Ductus Arteriosus (PDA) in Term and Preterm Neonates.

#### Protocol summary

##### Study aim

Determining and comparing the effect of injectable Acetaminophen in closure of Patent Ductus Arteriosus (PDA) in full term infants admitted.

##### Design

Clinical trial with control group, with parallel groups, single blind, randomized, phase 3 on 80 patients. Simple randomization was used for randomization.

##### Settings and conduct

The study was conducted as a randomized, single-blind clinical trial on term infants hospitalized in the special care department of Afzalipur Hospital, Kerman. PDA diagnosis was confirmed by echocardiography on the third day after birth and according to symptoms. Infants were selected by convenient method and were placed in two intervention and control groups by a simple random method.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: All term babies 37 weeks and more hospitalized due to patent ductus arteriosus, who were at least 3 days old and at most 28 days old; Exclusion Criteria: Congenital heart defects, multiple congenital anomalies, asphyxia, life-threatening disease, Lack of parental consent.

##### Intervention groups

Intervention group: The intervention included the use of injectable acetaminophen manufactured by Amin Pharmaceutical Company with a dose of 20 mg based on weight in the first hour and 10 mg based on weight every six hours for three days after the initial dose. Control group : Term infants with patent ductus arteriosus receiving normal saline with the same volume as the drug

##### Main outcome variables

Closure of ductus arteriosus

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230219057459N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **retrospective**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

##### Registration date

2023-06-24, 1402/04/03

##### Registrant information

##### Name

Marjan Nikvarz

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3271 0683

##### Email address

nikvarzmarjan@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2020-03-20, 1399/01/01

##### Expected recruitment end date

2022-03-19, 1400/12/28

##### Actual recruitment start date

2020-03-20, 1399/01/01

##### Actual recruitment end date

2022-03-19, 1400/12/28

##### Trial completion date

2022-03-19, 1400/12/28

##### Scientific title

A comparative study of the effectiveness of injectable Acetaminophen in closing Patent Ductus Arteriosus (PDA) in Term and Preterm Neonates.

## Public title

Investigating the effect of injectable Acetaminophen in the treatment of Patent Ductus Arteriosus (PDA).

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

All hospitalized neonates with Patent Ductus Arteriosus(PDA) All term neonates with a gestational age of 37 weeks and more The minimum age is 3 days and the maximum age is 28 days.

### Exclusion criteria:

Congenital Heart Disease Multiple Congenital Anomalies Life Threatening Disease Asphyxia Lack of parental consent

## Age

From **3 days** old to **28 days** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Data analyser

## Sample size

Target sample size: **80**

Actual sample size reached: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The rand function of Excel software was used for randomization. Based on the random number obtained in the software, the infants are divided into two groups (intervention and control) and this process will continue for each group up to 40 people.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, the researcher is informed about the division of the groups, also the parents of the babies have received explanations about the objectives and how to conduct the research, but parents and babies do not know about the division of the groups (intervention or control). Also, the statistician analyzing the data does not know which of the groups the data collected during the study belongs to, and the coded data in two groups (A and B) were given to the expert and their analysis was done.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

## Ethics committee

### Name of ethics committee

Ethics Committee of Afzalipur Medical Education Center - Kerman University of Medical Sciences

### Street address

Afzalipur Hospital, Imam Khomeini Highway, Kerman town

### City

Kerman

### Province

Kerman

### Postal code

7616913355

## Approval date

2022-01-10, 1400/10/20

## Ethics committee reference number

IR.KMU.AH.REC.1400.243

## Health conditions studied

## 1

## Description of health condition studied

Neonatal Patent Ductus Arteriosus

## ICD-10 code

Q25.0

## ICD-10 code description

Patent ductus arteriosus

## Primary outcomes

## 1

## Description

Closure of patent ductus arteriosus in neonates.

## Timepoint

Opening of the ductus arteriosus: before the start of the study and on the third day and the sixth day after receiving injectable acetaminophen

## Method of measurement

Eco cardiography

## Secondary outcomes

empty

## Intervention groups

## 1

## Description

The intervention group: included the use of injectable acetaminophen by Amin company with a dose of 20 mg based on weight, in the first hour and 10 mg based on weight, for every six hours, for three days after the initial dose.

## Category

Treatment - Drugs

## 2

### Description

Control group: included the use of normal saline injection with a volume equal to the drug in the first hour and every six hours for three days after the initial dose.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Afzalipoor Hospital

##### Full name of responsible person

Mohammad Mehdi Bagheri

##### Street address

Afzalipur Hospital, Imam Khomeini Highway, Kerman town

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913355

##### Phone

+98 34 3132 8000

##### Email

mehdi\_b\_ped@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Reza Malekpour Afshar

##### Street address

research and technology department, at the beginning of Ibn Sina street, Somaye intersection (Tahmasabad), Kerman

##### City

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##### Province

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##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

No

##### Title of funding source

Kerman University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Mohammad Mehdi Bagheri

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Pediatrics

#### Street address

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Mohammad Mahdi Bagheri

#### Position

Associate professor

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available