

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

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Name of organization / entity

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Iran (Islamic Republic of)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

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

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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

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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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