Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

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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
Ebnesina 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
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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

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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