Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Evaluating the effect of prophylactic Acetaminophen in the prevention PDA (Patent Ductus Arteriosus) in premature neonates: The randomized clinical trial

Protocol summary

Study aim

Investigating the effect of prophylactic acetaminophen in the prevention of patent ductus arteriosus (PDA) in premature infants with a gestational age of less than 30 weeks.

Design

In this randomized clinical trial study, premature newborn with gestational age less than 30 weeks who were admitted to the NICU of Imam Reza Hospital will be included in the study. The newborn will be randomly divided into case and control groups. A blind randomization will be done by sealed envelopes. Newborn in the intervention group will receive paracetamol a dose of 10 mg/kg every 6 hours for three days. Newborn in the control group (no placebo)

Settings and conduct

Randomized clinical trial study, premature newborn with gestational age less than 30 weeks who admitted to the NICU of Imam Reza Hospital. The babies will be randomly divided into case and control groups. A blind randomization will be done by sealed envelopes

Participants/Inclusion and exclusion criteria

Inclusion criteria: premature newborn with a gestational age of less than 30 weeks, premature babies who do not have evidence of patent ductus arteriosus. Exclusion criteria: CHF, Presence of liver or kidney disease or cholestasis, Presence of congenital heart disease, PPHN, Genetic disorder and congenital malformations, 5-minute Apgar score less than 5, pH < 7.2, septicemia, Sickness of the patient, The difference in pre-duct and post-duct oxygen saturation is more than 3%

Intervention groups

In the intervention group, premature newborn with a gestational age of less than 30 weeks will receive injectable acetaminophen at 10 mg/kg every 6 hours for 3 days. In the control group (no placebo), premature newborn with a gestational age of less than 30 weeks will not receive any special drug.

Main outcome variables

The frequency of failure to develop patent ductus arteriosus in premature infants with a gestational age of less than 30 weeks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081021001378N15**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-29, 1402/02/09**
Update count: **0**

Registration date

2023-04-29, 1402/02/09

Registrant information

Name

Ahmadshah Farhat

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date
2024-01-21, 1402/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of prophylactic Acetaminophen in the prevention PDA (Patent Ductus Arteriosus) in premature neonates: The randomized clinical trial

Public title
effect of prophylactic Acetaminophen in the prevention PDA (Patent Ductus Arteriosus) in premature neonates
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Consent to participate in the study Premature babies with a gestational age of less than 30 weeks Premature infants without evidence of patent ductus arteriosus
Exclusion criteria:
CHF Liver or kidney disease or cholestasis congenital heart disease PPHN Genetic disorders and congenital malformations Apgar score 5 minutes less than 5 PH <7.2 Septicemia Difference in pre-duct and post-duct oxygen saturation is more than 3%
Age
From **1 day** old to **30 days** old
Gender
Both

Phase
1-2
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Random number table using www.sealedenvelope.com In the randomization part of the site, after selecting create a list, it specifies the number of 2 groups in block sizes of 5 and based on that, it presents the randomization list.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is an one-blind clinical trial where both the participants and all the researchers related to the patients are unaware of the patient's exposure.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad university of Medical Sciences
Street address
Ghoreshi Bul, Daneshgah Ave, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2022-06-21, 1401/03/31
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.328

Health conditions studied

1

Description of health condition studied
Patent ductus arteriosus
ICD-10 code
Q25.0
ICD-10 code description
Patent ductus arteriosus

Primary outcomes

1

Description
Evaluating the effect of prophylactic acetaminophen intervention on the clinical manifestations of premature infants with a gestational age of less than 30 weeks
Timepoint
every 6 hours for three days.
Method of measurement
The first dose will be prescribed after 12 hours of birth to provide enough time to examine the baby for underlying cardiac pathology, then every 6 hours for three days.

Secondary outcomes

1

Description
Sepsis
Timepoint
Every 6 hours for three days
Method of measurement
through laboratory tests

2

Description
Intraventricular hemorrhage
Timepoint
Every 6 hours for three days
Method of measurement
By sonography of the skull through the anterior fontanel

3

Description
Retinopathy of prematurity
Timepoint
Every 6 hours for three days
Method of measurement
Use of Ret Cam

4

Description
Bronchopulmonary dysplasia
Timepoint
Every 6 hours for three days
Method of measurement
Newborn age and oxygen need

Intervention groups

1

Description
Intervention group: Premature newborn with a gestational age of less than 30 weeks will receive intravenous acetaminophen at 10 mg/kg every 6 hours for up to 3 days.
Category
Treatment - Drugs

2

Description
Control group: Premature newborn with a gestational age of less than 30 weeks will not receive any special medicine.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital, Mashhad, Iran
Full name of responsible person
Samira Alinezhad
Street address
Neonatal Intensive Care Unit, Imam Reza Hospital, Ibn Sina Ave, Mashhad, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Samira Alinezhad
Position
Neonatology
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

Title and more details about the data/document
All data can be shared after patients are made unidentified

When the data will become available and for how long
data can be accessible 6 months after results are published

To whom data/document is available
Data can be accessible through an email to the corresponding author

Under which criteria data/document could be used
Data will be available for researchers in universities and other scientific institutions

From where data/document is obtainable
After sending a request email to the corresponding author data will be sent in 2 month

What processes are involved for a request to access data/document
Carrying out analysis on data is permitted

Comments