

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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farhata@mums.ac.ir

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 scientific inquiries

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Full name of responsible person

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Latest degree

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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