Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of different oral and injectable paracetamol formulations on the rate and speed of PDA closure in stable preterm infants, based on the El-Khuffash scoring system.

Protocol summary

Study aim
Comparison of the closure rate of a patent ductus arteriosus between oral and intravenous paracetamol in hemodynamically stable preterm infants

Design
This is a Phase 3, randomized, triple-blind, parallel-group, controlled clinical trial involving 98 premature infants, in which the randomization process is performed using the random function in Microsoft Excel.

Settings and conduct
In the NICU at Shohadaye Tajrish Teaching Hospital, echocardiography will be performed prior to the initiation of acetaminophen, as well as three and five days after the start of the medication. The infants' parents are unaware of the specific drug formulation used. Blinding is maintained for the principal investigator, healthcare staff (including other physicians and nurses), the outcome assessor, the data analyst, and the Data Safety and Monitoring Committee.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Preterm infants up to 3 days of age with stable hemodynamics, a clinically significant patent ductus arteriosus, and written informed consent for participation in the study. Exclusion criteria: Term infants, infants older than 3 days, unstable hemodynamic status, and lack of consent from the parents or the infant's legal guardian.

Intervention groups
Ninety-eight preterm infants with clinically significant PDA will be enrolled in the study. Using a block randomization method, they will be equally assigned to two groups: the first group will receive paracetamol orally, while the second group will receive it intravenously. The dosage, administration intervals, and duration of treatment in both groups will follow the established treatment protocol, and the targeted outcomes will be evaluated and compared between the two groups.

Main outcome variables
Demographic data, hemodynamic assessment indices (echocardiography), type of acetaminophen formulation and duration of use, and laboratory tests.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261024071550N1**
Registration date: **2026-10-28, 1405/08/06**
Registration timing: **prospective**

Last update: **2026-10-28, 1405/08/06**
Update count: **0**

Registration date
2026-10-28, 1405/08/06

Registrant information

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Name of organization / entity

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-11-21, 1405/08/30

Expected recruitment end date
2027-02-19, 1405/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of different oral and injectable paracetamol formulations on the rate and speed of PDA closure in stable preterm infants, based on the El-Khuffash scoring system.

Public title
The effect of different paracetamol pharmaceutical formulations (oral and injectable) on the rate and extent of PDA closure in preterm infants, based on the El-Khuffash scoring system.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age at birth < 37 weeks Postnatal age between 24 and 72 hours Diagnosis of a clinically significant PDA, based on an El-Khuffash PDA score ≥ 5, indicating a need for pharmacological treatment Stable hemodynamic status Written informed consent from parents or a legal guardian
Exclusion criteria:
Gestational age greater than 37 weeks Age of the premature infant is over 3 days Unstable hemodynamic status Lack of written informed consent from the parents or legal guardian of the infant
Age
From **1 day** old to **3 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
A unique code was assigned to each participant using a random sequence generated by the `RAND` function in Microsoft Excel. Subsequently, participants were allocated to study groups based on these codes and in accordance with the predetermined allocation ratio. To prevent the prediction of group assignment, the random sequence was generated by an individual independent of the participant recruitment and assessment process and was kept concealed until the time of allocation.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The parents are informed that their infant requires pharmacological closure of a patent ductus arteriosus (PDA), but they are not told which specific drug formulation is being used. The principal investigator, who performs the echocardiograms, records only the echocardiographic data, remaining blinded to both the specific drug formulation and the infant's demographic information. Healthcare staff—including other physicians and nurses responsible for the infants' care—are unaware of which infants are enrolled in the research study. The data assessor, the data analyst, and the Data Safety and Monitoring Committee have no contact with the infants' parents or the principal investigator; their focus is exclusively on the study data.
Placebo
Not used
Assignment
Parallel
Other design features
To date, there has been no precise criterion for selecting the type of pharmaceutical formulation of acetaminophen for the closure of a patent ductus arteriosus (PDA) in premature infants, and no study has been conducted on this subject.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of the Shahid Beheshti Faculty of Medical Sciences
Street address
Research Center for Ethics and Law in Medicine, Shahid Beheshti University of Medical Sciences, 1st Floor, No. 8, Shams Alley, before Tavanir St., Valiasr St., Tehran
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Postal code
88777539
Approval date
2026-10-20, 1405/07/28
Ethics committee reference number
IR.SBMU.MSP.REC.1405.529

Health conditions studied

1

Description of health condition studied
Patent ductus arteriosus in premature infants
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Hemodynamic parameters in echocardiography
Timepoint
Before the start of the study, and 3 and 5 days after the start of the study
Method of measurement
Using an echocardiography machine with a specialized probe for infants

Secondary outcomes

empty

Intervention groups

1

Description
Group 1 (Oral Paracetamol): Eligible preterm infants with clinically significant PDA will receive paracetamol orally, at the dosage and dosing intervals specified in the study protocol.
Category
Treatment - Drugs

2

Description
Control group:Group 2 (Intravenous Paracetamol) – Eligible preterm infants with clinically significant PDA will receive paracetamol intravenously, at the dosage and administration intervals specified in the study protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU Department, Shohada Tajrish Hospital
Full name of responsible person
Dr. Maryam Taraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Web page address
Grant name
0
Grant code / Reference number
0
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
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Assistant Professor and Faculty Member, Pediatric Cardiologist (Subspecialist)
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Person responsible for updating data

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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