Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of efficacy rate of prophylactic treatment with oral paracetamol for closure of patent ductus arteriosus in preterm infants admitted in neonatal intensive care unit

Protocol summary

Summary

The aim of the study is investigating the efficacy rate of prophylactic treatment with oral paracetamol for closure of patent ductus arteriosus in preterm infants. Inclusion criteria is premature neonates born at or before 32 weeks of gestation with birth weight less than or equal to 1500 grams and exclusion criteria is congenital major anomalies or chromosomal abnormalities. This interventional study will performed in premature newborns who admitted in neonatal intensive care unit of Vali-e-Asr Hospital in 2012-2013. Since thus far no studies have been conducted about the efficacy of acetaminophen for closure of patent ductus arteriosus, so 30 subjects are evaluated in this study. Subjects are randomly divided into 2 groups at beginning of admission. For the first group during first 24 hours after birth 15mg/kg oral acetaminophen will administrated every 6 hours for 48 hours. Echocardiography will performed for them during 24-36 hours after the last dose of acetaminophen by a pediatric cardiologist to evaluating of ductus arteriosus. Echocardiography of newborns in second group will also performed during 4-5 days old without any intervention by the same specialist to evaluate ductus arteriosus.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014090519050N1**
Registration date: **2015-02-02, 1393/11/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-02-02, 1393/11/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tehran university of medical sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-20, 1391/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of efficacy rate of prophylactic treatment with oral paracetamol for closure of patent ductus arteriosus in preterm infants admitted in neonatal intensive care unit

Public title

The efficacy of prophylactic treatment with oral acetaminophen for closure of patent ductus arteriosus in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Premature neonates born at or before 32 weeks of gestation with birth weight less than or equal to 1500 grams admitted in neonatal intensive care unit of Vali-e-Asr Hospital in 2012; parental consent for participating in this study. Exclusion criteria: Newborns with congenital heart defects that patency of ductus arteriosus is vital for them such as pulmonary atresia; congenital major anomalies or chromosomal abnormalities; maternal consumption of none steroidal anti-inflammatory drugs during pregnancy; newborns with hydrops fetalis or persistent pulmonary hypertension of the newborn; apgar score less than 5 at fifth minute after birth; appearance of patent of dutus arteriosus symptoms and requirement for treatment with Ibuprofen at any time; having vomiting or hematemesis during first 3 days after birth; neonates with glucose-6-phosphate dehydrogenase deficiency based on blood exam at beginning of neonatal admission

Age

To **6 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethical Committee of Tehran University of Medical Science

Street address

The Ethical Committee of Tehran University of Medical Science, Vice Chancellor for research, 6th Floor, Tehran University of Medical Sciences, Corner of Ghodss Street, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2013-08-04, 1392/05/13

Ethics committee reference number

905/130/92/د

Health conditions studied

1

Description of health condition studied

patent ductus arteriosus

ICD-10 code

Q25.0

ICD-10 code description

Congenital malformations of great arteries

Primary outcomes

1

Description

Left Atrial to Aortic Ratio

Timepoint

4-5 day of life

Method of measurement

Echocardiography

2

Description

Internal Ductal Diameter

Timepoint

4-5 day of life

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of 15mg/kg oral acetaminophen every 6 hours for 48 hours during first 24 hours after birth

Category

Treatment - Drugs

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex, Vali-Asr Hospital
Full name of responsible person
Dr.Mohamad Reza Zarkesh
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Sponsors / Funding sources

1

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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
Vice Chancellor for research of Tehran 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

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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