Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of short and long term complications of treatment with oral ibuprofen versus fluid restriction in preterm infants with patent ductus arteriosus .

Protocol summary

Summary

Aim: Patent ductus arteriosus (PDA), is one of the most common congenital cardiac anomalies in premature infants. Nonsteroidal anti-inflammatory agents are the treatment of choice for ductal closure in premature newborn. As in Iran, the only available drug is oral ibuprofen; therefore the study was conducted to determine short and long-term complications as well as the effectiveness of oral ibuprofen in the treatment of PDA in premature infants. Including and excluding criteria: In this clinical trial, for all preterm infants below 38 weeks admitted at Amiralmomenin Hospital, with a murmur but without any symptoms of heart failure transthoracic echocardiography was performed, and with documentation of PDA they were enrolled in the study. Infants were divided into two groups. The neonates that have other cardiac problems except PDA ,neonates with unstable conditions, neonates with significant congenital heart disease and neonates whose mothers had taken nonsteroid anti-inflammatory substances were excluded. In addition to the first day and the third day of treatment, a third and sixth month echocardiography were performed in both groups, and the rate of PDA closure and the rate of pulmonary hypertension in both groups were compared.The presence of intraventricular hemorrhage and periventricular leukomalacia (PVL) were detected by brain ultrasound at the age of one week and one month. The presence of retinopathy was checked at the time of hospital discharge. Other findings such as duration of hospital stay, pulmonary hemorrhage, ventilator time dependence, duration dependence on oxygen and nosocomial infections were recorded.Then the obtained data in both groups were compared. During 12 months all neonates with the above criteria are included and a total number of 60 neoantes will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071113022N2**
Registration date: **2013-08-04, 1392/05/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

Name

Semira Mehralizadeh

Name of organization / entity

Semnan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2014-01-01, 1392/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of short and long term complications of treatment with oral ibuprofen versus fluid restriction in preterm infants with patent ductus arteriosus .

Public title
Comparison of short and long term complications of treatment with oral ibuprofen versus fluid restriction in preterm infants with patent ductus arteriosus .

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: All premature neonates with gestational age of less than 38 weeks:EKG with left axis deviation of prematurity:the neonates of having systolic murmur and bounding pulse .and the neonates with patent ductus arteriosus proved on echocardiography were included. Exclusion criteria: Those having other congenital heart disease than PDA:neonates with other congenital anomalies:neonates with clinical signs of congestive heart failure :the neonates of mothers taking nonsteroidal antiinflammatory agents during pregnancy

Age
To **1 year** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences

Street address
Smnan-Baseej Blvd

City
Semnan

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
can be attached

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
Ductal Closure

Timepoint
First day-3rd day-3rd month-6 months

Method of measurement
Echocardiography

2

Description
Pulmonary hypertension

Timepoint
1st day-3rd day-3rd month-6th month

Method of measurement
Echocardiography

Secondary outcomes

1

Description
Intraventricular hemorrhage

Timepoint
1st week-1st month

Method of measurement
sonography

2

Description
Periventricular leukomalacia

Timepoint
1st week-1st month

Method of measurement
sonography

3

Description
Retinopathy of prematuriity

Timepoint
At discharge

Method of measurement
Retinoscope

Intervention groups

1

Description
In the intervention group 3 doses of oral ibuprofen were prescribed with the dose of 5mg/kg on the first day and 10 mg/kg at 24 and 48 hours after the first dose.
Category
Treatment - Drugs

2

Description
The control group only received fluid restriction at the dose of 2/3 of maintenance dose required individually.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmonenin Hospital
Full name of responsible person
Dr Semira Mehralizadeh
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City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semann University of Medical Sciences-
Full name of responsible person
Dr Raheb Ghorbani
Street address
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Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semann 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