

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

The comparison of the incidence of pulmonary edema using two methods of anesthesia in pediatrics undergoing patent ductus arteriosus (PDA) surgery

Protocol summary

Summary

This study aimed at reducing the incidence of post-operative pulmonary edema in children undergoing patent ductus arteriosus ligation. The study is done randomly in two groups (120 patients are enrolled). In the intervention group, patient is given morphin and lasix after ligation of duct. The incidence of pulmonary edema in the intervention and control (without any intervention) group will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112098341N1**

Registration date: **2012-11-10, 1391/08/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-11-10, 1391/08/20

Registrant information

Name

Ahmad Ebadi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1374 3017

Email address

ebadi1959@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

1997-06-22, 1376/04/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the incidence of pulmonary edema using two methods of anesthesia in pediatrics undergoing patent ductus arteriosus (PDA) surgery

Public title

The comparison of the incidence of pulmonary edema using two methods of anesthesia in pediatrics undergoing PDA surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: isolated PDA patient aged 1_12 years; moderate and sever pulmonary HTN. Exclusion criteria: another structural abnormality.

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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**

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan st.

City

Ahvaz

Postal code**Approval date**

2011-11-12, 1390/08/21

Ethics committee reference number

eth-309

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**

pulmonary edema

Timepoint

every 1 hour for 24 hr

Method of measurement

auscultation/ABG

Secondary outcomes**1****Description**

Hypotension

Timepoint

each 15 min

Method of measurement

arterial line

Intervention groups**1****Description**

Intervention group: morphin 0.1 mg/kg & lasix 0.5 mg/kg.

Category

Treatment - Drugs

2**Description**

Control group: no drug

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ahvaz Golestan hospital

Full name of responsible person

Dr Ahmad Ebadi, assistant professor

Street address

cardiosurgery operating room in Ahvaz Golestan hospital

City

Ahvaz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Mostafa Fegghi

Street address

Golestan blvd

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz Jundishapur 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***Phone**

+98 61 1336 1984

Fax**Email**

ebadi1959@ajums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Shohreh Beladi Behbahani

Position

anesthesiology assistant

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code**Phone**

+98 61 1338 9329

Fax**Email**

shohrehbeladi@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Shohreh Beladi Behbahani

Position

Anesthesiology assistant

Other areas of specialty/work**Street address**Ahvaz Jundishapur University of Medical Sciences,
Golestan blvd**City**

Ahvaz

Postal code**Phone****Fax****Email**

shohrehbeladi@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Ahmad Ebadi

Position

assistan professor

Other areas of specialty/work**Street address**

Golestan Hospital

City

Ahvaz

Postal code**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*