

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparing the effects of Intermittent Positive Pressure Ventilation and Spontaneous Ventilation on Cardiorespiratory Parameters of Pediatric Patients less than 1 year old.

Protocol summary

Summary

Aims: We aimed to compare the effects of Intermittent Positive Pressure Ventilation and Spontaneous Ventilation on cardiorespiratory parameters of pediatric patients less than 1 year old, undergoing Angiography under general anesthesia. Inclusion and exclusion key criteria: Inclusion: Age below 1 year ; Candidate for elective cardiac angiography ; ASA class II. Exclusion: Refuse to accept informed consent ; History of co-existing respiratory or neural anomaly ; Having received sedatives prior to cath admission ; History of patient or mother drug abuse ; Body weight below 3kg ; birth weight below 2.5kg. Population Studied: Pediatric patients, under 1 year, candidate for cardiac angiography. Sample Size: 60 patients. Intervention: The candidates will be randomly assigned into two groups of Intermittent Positive Pressure Ventilation and Spontaneous ventilation. Induction with ketamine, intubation and maintenance of anesthesia with sevoflurane gas were performed. The first group: had respiratory support via Intermittent Positive Pressure Ventilation. The second group: breathe spontaneously. Primary Outcomes: Arterial oxygen saturation, arterial carbon dioxide tension, pulmonary to systemic arterial blood pressure and left atrial pressure will be evaluated during the procedure and then analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012920793N2**

Registration date: **2015-12-18, 1394/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-18, 1394/09/27

Registrant information

Name

Behrang Nooralishahi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 1030

Email address

b-nooralishahi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-10-01, 1394/07/09

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Intermittent Positive Pressure Ventilation and Spontaneous Ventilation on Cardiorespiratory Parameters of Pediatric Patients less than 1 year old.

Public title

Comparing the effects of Intermittent Positive Pressure Ventilation and Spontaneous Ventilation on

Cardiorespiratory Parameters of Pediatric Patients less than 1 year old, undergoing Angiography under general anesthesia. in Children's Medical Center, 2015

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age below 1 year ; Candidate for elective cardiac angiography ; ASA class II Exclusion Criteria: Refuse to accept informed consent ; History of co-existing respiratory or neural anomaly ; Having received sedatives prior to cath admission ; History of patient or mother drug abuse ; Body weight below 3kg ; birth weight below 2.5kg.

Age

From **14 days** old to **12 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Tehran University of Medical Sciences, Committee of ethics.

Street address

Tehran University of Medical Sciences, faculty of medicine.

City

Tehran

Postal code

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.TUMS.REC.1394.117

Health conditions studied

1

Description of health condition studied

Congenital Heart Disease

ICD-10 code

Q24

ICD-10 code description

Other congenital malformations of heart

2

Description of health condition studied

Congenital Heart Disease

ICD-10 code

Q25

ICD-10 code description

Congenital malformations of great arteries

3

Description of health condition studied

Congenital Heart Disease

ICD-10 code

Q26

ICD-10 code description

Congenital malformations of great veins

Primary outcomes

1

Description

Pulmonary to systemic arterial pressure ratio

Timepoint

Intra operative, within 2 hours.

Method of measurement

Invasive arterial pressure measurement.

Secondary outcomes

1

Description

Systemic arterial oxygen pressure

Timepoint

Intra operative, within 2 hours

Method of measurement

Arterial blood gas sampling

2

Description

Systemic arterial pressure of carbon dioxide

Timepoint

Intra operative, within 2 hours

Method of measurement

Arterial blood gas sampling

Intervention groups

1

Description

Intervention: Intermittent positive-pressure ventilation

Category

Other

2

Description

Control: Spontaneous Breathing

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Behrang Nooralishahi

Street address

Gharib st. Keshavarz ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhoondzadeh

Street address

Keshavarz Ave.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Behrang Nooralishahi

Position

Assistant Professor

Other areas of specialty/work

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Web page address

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