

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparative evaluation of the effects of continuous positive airway pressure and zero airway pressure during cardiopulmonary bypass on cardiac de-airing after open heart surgery in patients with rheumatic heart valves diseases.

Protocol summary

Summary

Aime of study: Evaluation of the effect of continuous positive airway pressure during cardiopulmonary bypass on cardiac de-airing after open heart surgery Inclusion criteria: Patients candidate for aorta and/or mitral valve with/without tricuspid valve replacement surgery; Ejection fraction >40%; Patients without heart surgery; absence of history of dysphasia, odinophagia and previous oesophageal surgery. Exclusion criteria: Intra aortic balloon while weaning from CPB. The study population was patients with rheumatismal heart valves disease that were scheduled for heart valve replacement surgery. Sample volume: 40 patients Intervention and outcome of study: This randomized prospective double blind clinical trial conducted on 40 patients. Control group: During cardiopulmonary pump, the ventilator was turned off and adjustable pressure limit (APL) valve was placed in Spont position. CPAP group: After turning the ventilator off, the flow of oxygen flow was maintained at the rate of 0.5L/min and the APL valve was placed in Man position on 20mbar. During CPB weaning, the patients were observed for air bubbles in left atrium by using TEE.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013043013181N1**
Registration date: **2013-09-11, 1392/06/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-11, 1392/06/20

Registrant information

Name

Mojtaba Mansouri

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1775 0252

Email address

mansouri@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of medical science

Expected recruitment start date

2012-03-19, 1390/12/29

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

Comparative evaluation of the effects of continuous positive airway pressure and zero airway pressure during cardiopulmonary bypass on cardiac de-airing after open heart surgery in patients with rheumatic heart valves diseases.

Public title

Effect of continues positive airway pressure on de-airing process.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate for aorta and/or mitral valve with/without tricuspid valve replacement surgery; Ejection fraction >40%; Patients without heart surgery; absence of history of dysphasia, odinophagia and previous oesophageal surgery. Exclusion criteria: Intra aortic balloon while weaning from CPB.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Isfahan univesity of medical science

Street address

Isfahan, Hezar Jarib St.

City

Isfahan

Postal code

Approval date

2012-02-01, 1390/11/12

Ethics committee reference number

390539

Health conditions studied

1

Description of health condition studied

cardiac chamber de-airing

ICD-10 code

I05, I06,

ICD-10 code description

Chronic rheumatic heart diseases

Primary outcomes

1

Description

Time of de-airing

Timepoint

from mechanical ventilation bigining untill end of de-airing process

Method of measurement

minute

2

Description

amount of air bubble in left atrium cavity durig de-airing

Timepoint

from mechanical ventilation bigining untill end of de-airing process

Method of measurement

scale: mild, moderate, sever

Secondary outcomes

empty

Intervention groups

1

Description

After turning the ventilator off, the flow of oxygen flow was maintained at the rate of 0.5L/min and the APL valve was placed in "Man" position on 20 mbar (20 hectopascal, 15mmHg).

Category

Prevention

2

Description

During the surgery and CPB, the ventilator (Drager, Fabius) was turned off and the flow of fresh air was totally ceased and adjustable pressure limit (APL) valve was placed in "Spont" position.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran heart hospital

Full name of responsible person

Mojtaba Mansouri

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan university of medical science

Full name of responsible person

Taleb Azarm

Street address

isfahan medical school

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan university of medical science

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

Isfahan Medical School

Full name of responsible person

Mijtaba Mansouri

Position

Associate 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