

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of CPAP masks on hemodynamic parameters, arterial blood gas and pulmonary complications in patients after open heart surgery

Protocol summary

Summary

This study aimed to investigate the effects of continuous positive airway pressure masks on hemodynamic parameters after open heart surgery. A randomized controlled trial was conducted on 72 patients undergoing open heart surgery that were randomly assigned into two groups of intervention (n = 36) and control (n = 36) in Iran, 2015. After the extubation, a continuous positive airway pressure mask (with a force of 5 cmH2o) used for patients in the intervention group (30 minutes every eight hours for five consecutive times). Measurements: A checklist was used to record the hemodynamic parameters(SBP,DBP,MAP,CVP,HR) and ABG of all patients 10 minutes before and after each intervention. pulmonary complication(pneumonia, atelectasia, plural effusion)was record in end of study. Data analysis was performed using Kolmogorov-Smirnov test, t-test and chi-square.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902013146N2**

Registration date: **2016-08-18, 1395/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-18, 1395/05/28

Registrant information

Name

Ismail Azizi-Fini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kashan university of medical science

Expected recruitment start date

2015-12-10, 1394/09/19

Expected recruitment end date

2016-06-07, 1395/03/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of CPAP masks on hemodynamic parameters, arterial blood gas and pulmonary complications in patients after open heart surgery

Public title

The effect of CPAP masks on hemodynamic parameters, arterial blood gas and pulmonary complications in patients after open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age > 18 years; having an elective of surgery; undergoing cardiopulmonary bypass (CPB) during cardiac surgery; having an EF over 40%; having at least a chest tube in the pleural cavity; being under mechanical ventilation for less than 12 hours after the surgery. Exclusion criteria: no need for medications such as epinephrine, dopamine, and dobutamine at the start of the study; lacking a definite diagnosis of COPD and asthma.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics commete of Kashan University of Medical Sciences

Street address
Blv Ghotb Ravandi, Blv Pezeshk, Kashan University of Medical Sciences

City
kashan

Postal code
8715981151

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

Ethics committee reference number
Ir.KAUMS.REC.1394.116

Health conditions studied

1

Description of health condition studied
plural effusion

ICD-10 code
J91

ICD-10 code description
Pleural effusion in conditions classified elsewhere

2

Description of health condition studied
Atelectasis

ICD-10 code

J98

ICD-10 code description
Pulmonary collapse

3

Description of health condition studied
pneumonia

ICD-10 code
J15

ICD-10 code description
Bacterial pneumonia, not elsewhere classified

4

Description of health condition studied
Hemodynamic

ICD-10 code
I99

ICD-10 code description
Other and unspecified disorders of circulatory system

Primary outcomes

1

Description
Diastolic BP

Timepoint
pre and 10 min post Intervention

Method of measurement
monitor

2

Description
Heart Rate

Timepoint
pre and 10 min post Intervention

Method of measurement
monitor

3

Description
Central Venous Pressure

Timepoint
pre and 10 min post Intervention

Method of measurement
monitor

4

Description
Atelectasy

Timepoint
end of Study

Method of measurement
CXRay

5

Description

Systolic BP
Timepoint
pre and 10 min post Intervention
Method of measurement
monitor

6

Description
Plural Effusion
Timepoint
end of Study
Method of measurement
CXRay

7

Description
Mean arterial pressure
Timepoint
pre and 10 min post Intervention
Method of measurement
monitor

8

Description
pneumonia
Timepoint
end of Study
Method of measurement
CXRay

Secondary outcomes

1

Description
Ejection Fraction
Timepoint
end of study
Method of measurement
Echocardiography

Intervention groups

1

Description
. After the extubation, a continuous positive airway pressure mask (with a force of 5 cmH2o) used for patients in the intervention group (30 minutes every eight hours for five consecutive times).
Category
Treatment - Devices

2

Description
control group:NO treat ment
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Street address
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research OF Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidi
Street address
Blv Ghotb Ravandi, Blv Pezeshk, Kashan University of Medical Sciences
City
Kashan
Grant name
7153
Grant code / Reference number
94116
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research OF Kashan 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
Kashan University of Medical Sciences
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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