Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Study the effect of Active Cyclic breathing technique on arterial blood gas measures in patient undergoing open heart surgery

Protocol summary

Study aim
Determine the effect of the active respiratory cycle technique on arterial blood gases

Design
A clinical trial with a control group, with a parallel, double-blind, randomized, clinical trial

Settings and conduct
After obtaining permission from the ethics committee in the research of Rafsanjan University of Medical Sciences and presenting a referral to the deputy of the Kerman University of Medical Sciences and obtaining informed consent from the patients, one of the researchers will sample. The initial arrival of the samples is based on the target and then in a randomized manner, minimization, will be placed in two groups of intervention and control, so that both groups will be matched in terms of gender and cause of open heart surgery. The first sample will be entered in classes in a simple random order and then based on the total number of samples in each class.

Participants/Inclusion and exclusion criteria
Patient entry criteria include: Age aged 18-60 years; Sternotomy with or without valve replacement

Intervention groups
There are two intervention and control groups in this study. In the intervention group, the active respiratory cycle technique is implemented in two days and the routine physiotherapy control group is performed.

Main outcome variables
The average amount of arterial blood gas before and after intervention in two consecutive days

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180304038935N1**
Registration date: **2018-06-27, 1397/04/06**
Registration timing: **registered_while_recruiting**
Last update: **2018-06-27, 1397/04/06**
Update count: **0**

Registration date
2018-06-27, 1397/04/06

Registrant information

Name
Ahmad Salehi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study the effect of Active Cyclic breathing technique on arterial blood gas measures in patient undergoing open heart surgery

Public title
Study the effect of Active Cyclic breathing technique on arterial blood gas measures

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age aged 18-60 years Performing a wind sternotomy or without switching the valve The patient is able to speak and understand Persian language Inclination to participate in research
Exclusion criteria:

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
This study was a randomized clinical trial with control group. The initial arrival of the samples is based on the target and then in a randomized manner(minimization) will be placed in two groups of intervention and control, so that both groups will be matched in terms of gender and cause of open heart surgery. The first sample will be entered in classes in a simple random order and then based on the total number of samples in each class.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the participants are evaluated and blinded to the outcome, so that after a complete explanation of the method of implementation and the stages of the study and obtaining the written consent of patients, they are divided into two groups of intervention and control in the routine physiotherapy control group And the respiratory cycle is performed in the intervention group, but the patient does not know which physiotherapy has been received. In this study, the individual who evaluated the response to arterial blood gas tests does not have any information on the participants in the intervention and control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences

Street address
Central Organization, Imam Blvd , Rafsanjan

City
Rafsanjan

Province
Kerman

Postal code
7717933777

Approval date
2018-04-18, 1397/01/29

Ethics committee reference number
IR.RUMS.REC.1397.010

Health conditions studied

1

Description of health condition studied
Respiratory problems in patients undergoing open heart surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Arterial blood gas levels

Timepoint
During the two days after the extubation of the trachea before and after the respiratory physiotherapy, the amount of arterial blood gas is measured.

Method of measurement
The GEM Premier 3000 device is used to measure arterial blood gases

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For the intervention group, the active respiratory cycle technique is performed one day each day during the two days after the extubation of the trachea.

Category
Other

2

Description
Control group: A routine respiratory physiotherapy that will stimulate coughing and use a breathable vibrator in two days after the end of the tracheal tube.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shafa Hospital in Kerman
Full name of responsible person
Dr.Tayebe Negahban
Street address
Shafa Hospital, Kowsar Boulevard, Kerman, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr.Hamid Hakimi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rafsanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ahmad Salehi Derakhtanjani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available