

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 34 3315 0007

Email address

ahmadsalehi2117@yahoo.com

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

City

Kerman

Province

Kerman

Postal code

7717933777

Phone

+98 35 3626 0001

Fax

+98 34 3211 5783

Email

shafahospital@kmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr.Hamid Hakimi

Street address

Central Organization, Imam Ali Blvd, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0028

Fax

Email

info@rums.ac.ir

Web page address

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

Nursery

Street address

Al-Zahra Sub, Alley No12, Hakim St, Kerman

City

Kerman

Province

Kerman

Postal code

7615977118

Phone

+98 343315007

Email

Ahmadsalehi2117@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Tayebeh Negahban

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Central Organization, Imam Ali Blvd, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

negahbant@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Shahin Heydari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Central Organization, Blvd Imam Ali, Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Phone

+98 34 3428 0038

Email

Kermanshah3252@yahoo.com

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