

# 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

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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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Central Organization, Imam Ali Blvd, Rafsanjan

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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**

Nursery

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## Person responsible for scientific inquiries

### Contact

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Tayebeh Negahban

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Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Position**

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**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