

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of Respiratory Physiotherapy before Surgery on Pulmonary Complications in Patients Undergoing Cardiac valve Surgery

Protocol summary

Study aim

Determining the effect of preoperative respiratory physiotherapy on pulmonary complications in patients undergoing heart valve surgery

Design

Clinical trial with control and experience group. About 80 patients. The blocking method will be used as random quadruple blocks.

Settings and conduct

This study is a randomized clinical trial that will be performed at the Shahid Rajaei Cardiovascular Training, Treatment and Research Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) Patients who are candidates for heart valve surgery (mitral, aortic or tricuspid) 2) Age 18 to 65 years 3) Satisfaction to participate in the study 4) No history of heart surgery

Intervention groups

Due to the fact that respiratory physiotherapy is performed in most centers after surgery and not enough information is available on the effects of preoperative respiratory physiotherapy on faster recovery and control of complications, the present study aimed to investigate the effect of preoperative respiratory physiotherapy on complications. Pulmonary surgery will be performed in patients undergoing heart surgery. Intervention group: The researcher will teach the experimental group how to perform daily respiratory physiotherapy for 20 minutes from 15 days before surgery and will provide them with a pamphlet on how to perform the exercises. Incentive spirometry will also be provided to the experimental group. The experimental group will perform scheduled respiratory physiotherapy before surgery Control group: will receive routine hospital treatment, including postoperative breathing exercises and spirometry.

Main outcome variables

Arterial blood gases Mean respiratory volume using incentive spirometry • Pneumonia • atelectasis Intubation time • ICU admission time • Time of

hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211119053108N1**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Hamed Bayati shamseki

Name of organization / entity

Shahid rajaei heart center

Country

Iran (Islamic Republic of)

Phone

+98 21 3421 5785

Email address

hamedbayati700@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-31, 1400/10/10

Expected recruitment end date

2022-03-01, 1400/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Respiratory Physiotherapy before Surgery on Pulmonary Complications in Patients Undergoing Cardiac valve Surgery

Public title

Respiratory Physiotherapy before Surgery and Pulmonary Complications

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for heart valve surgery (mitral, aortic or tricuspid) No history of heart surgery No neuromuscular disorders or cognitive disorders No emergency surgery

Exclusion criteria:

Dissatisfaction with participating in the study Be lung and kidney healthy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The candidate for heart valve surgery will select the available method based on the inclusion criteria and randomly assign a block to one of the experimental (40) or control (40) groups. For random assignment to the experimental or control group, the blocking method will be used in the form of four random blocks. The letter A belongs to the intervention group and the letter B belongs to the control group. Based on. The sample size is 80 people. Blocking is used in the form of four blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Rajaei Heart Center

Street address

Tehran - Vali Asr St. (AS) - Next to Mellat Park - Corner of Niayesh Shahid Rajaei Cardiovascular Training, Research and Treatment Center

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.RHC.REC.1399.141

Health conditions studied**1****Description of health condition studied**

Pulmonary complications . cardiovascular patients

ICD-10 code

.

ICD-10 code description

.

Primary outcomes**1****Description**

Determining and comparing the mean results of arterial blood gases in the intervention and control groups, before surgery and three days after surgery

Timepoint

Before surgery and 3 days later

Method of measurement

Measurement using arterial blood gas test results

2**Description**

- Determination and comparison of mean respiratory volume using incentive spirometry in the intervention and control groups, before, three days and six days after surgery

Timepoint

Before surgery and 3 days later and 6 days later

Method of measurement

Based on the volume determined by the incentive spirometer

3**Description**

Determination of clinical and radiographic symptoms of pneumonia and atelectasis in the intervention group compared with the control group before, three days and six days after surgery

Timepoint

Before surgery and 3 days later and 6 days later

Method of measurement

Based on clinical examination and chest x-ray

4

Description

Determining and comparing the mean duration of intubation and hospitalization time in the intensive care unit and hospitalization in the intervention and control groups

Timepoint

Duration of hospitalization

Method of measurement

Based on hospital information

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The start of TFS physiotherapy is 15 days before surgery. In the clinic of Shahid Rajaei Hospital, pamphlets related to breathing exercises and incentive spirometry are provided to the patient and the necessary training on how to perform respiratory physiotherapy and use of incentive spirometry is given through lectures and shows. The patient is given. To ensure the effectiveness of the training, the patient is asked to once use the method of using incentive spirometry and how to perform respiratory physiotherapy in the presence of the researcher, and in case of problems at any stage, the training will be repeated. Preoperative physiotherapy techniques for patients will include the following: 1. Breathing exercises consisting of 10 attempts at deep breathing and diaphragmatic breathing 2. 10 breathing lip buds 3. Neck and shoulder exercises with emphasis on chest rehabilitation 4. Muscle tension exercises 5. Exercises to strengthen the muscles responsible for moving the shoulders back and forth (Shakoori et al., 2015). 6. Use of incentive spirometry (IS) (Respiflow™ FS) and effective cough

Category

Treatment - Devices

2

Description

Control group: The usual hospital treatments are performed on the control group

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Heart Center

Full name of responsible person

Dr. Saeed Hosseini

Street address

Tehran - Vali Asr St. (AS) - Next to Mellat Park - Corner of Niayesh Shahid Rajaei Cardiovascular Training, Research and Treatment Center

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Phone

+98 21 23921

Email

hamedbayati700@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Rajaei Heart Center

Full name of responsible person

Vice Chancellor for Research, Dr. Maleki

Street address

Tehran, Shariati St., Kaleem Kashani St., Daryani Alley, No. 52, Unit 2

City

Tehran

Province

Tehran

Postal code

1613773911

Phone

+98 21 3421 5785

Email

hamedbayati700@gmail.com

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Rajaei Heart Center

Full name of responsible person

Saeed Hosseini

Position

Subspecialty physician

Latest degree

Subspecialist

Other areas of specialty/work

Cardiac surgeon

Street address

Shariati St., Kaleem Kashani St., Daryani Alley, No. 52, Unit 2

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Rajaei Heart Center

Full name of responsible person

Saeed Hosseini

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Rajaei Heart Center

Full name of responsible person

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Participant data

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

People working in scientific institutes

Under which criteria data/document could be used

In order to be used for scientific work

From where data/document is obtainable

By email and phone number

What processes are involved for a request to access data/document

Send requests from individuals and then review and send responses

Comments