# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

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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
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahid Rajaei Heart Center
**Full name of responsible person**
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**Position**
Subspecialty physician
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Cardiac surgeon
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahid Rajaei Heart Center
**Full name of responsible person**
Saeed Hosseini
**Position**
Subspecialty physician
**Latest degree**
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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**