

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effects of respiratory rehabilitation before mitral valve surgery on the prevention of respiratory functions and complications and length of stay during admission in intensive car

Protocol summary

Study aim

Determination of the effect of respiratory training prior to mitral valve surgery in the prevention of impaired function and respiratory complications and duration of admission to special care units

Design

Clinical trial with control group, with parallel groups, blind, randomized

Settings and conduct

Sampling from patients referring to the Shahid Rajaei Cardiology Center in Tehran, which requires a mitral valve surgery (with / without need for aortic valve surgery) to be diagnosed by a specialist. Patients will be randomly assigned to one of the two groups. One-way blind is used, and the Surgeon is unaware of the control.

Participants/Inclusion and exclusion criteria

The criteria for admission to the project are: at least 18 years of age, left ventricular ejection fraction (LVEF) under 55% that will be measured by echocardiography, and no recent surgery of the heart or chest, and no musculoskeletal disorders and asthma and chronic obstructive pulmonary disease. Also, the exclusion criteria of the project are: recent surgery of the heart or chest, musculoskeletal disorders, asthma, chronic obstructive pulmonary disease (COPD), chronic pulmonary disease such as bronchitis, recent pulmonary infection, use of suppressing drugs Safety and non-consent of the patient by entering the plan and the terms of the consent form.

Intervention groups

For 30 days before surgery, the group carries out a non-exercise physiotherapy intervention (using a power breathing machine). The control group does not perform respiratory physiotherapy.

Main outcome variables

Duration of hospitalization in the field of intensive care and postoperative complications of mitral valve surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180430039480N1**

Registration date: **2018-07-30, 1397/05/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-30, 1397/05/08**

Update count: **0**

Registration date

2018-07-30, 1397/05/08

Registrant information

Name

Mandana Mashhadijafari

Name of organization / entity

University of Hospital Rajaei

Country

Iran (Islamic Republic of)

Phone

+98 21 7715 0680

Email address

mandanajafari1348@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of respiratory rehabilitation before mitral valve surgery on the prevention of respiratory functions and complications and length of stay during admission in intensive car

Public title

Evaluating the effects of respiratory rehabilitation before mitral valve surgery on the prevention of respiratory functions and complications and length of stay during admission in intensive car

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The criteria for entering the plan are: at least 18 years of age, left ventricular ejection fraction (LVEF) below 55% that will be measured by echocardiography, and no recent surgery of the heart or chest, and no musculoskeletal disorders and Asthma and Chronic Obstructive Pulmonary Disease

Exclusion criteria:

Exit criteria for a patient include: recent surgery of the heart or chest, musculoskeletal disorders, asthma, chronic obstructive pulmonary disease (COPD), chronic pulmonary disease, such as bronchitis, recent pulmonary infections, use of suppressing drugs and Disagreement with the patient entering the plan and the terms of the consent form

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize block.

Blinding (investigator's opinion)

Single blinded

Blinding description

The only surgery that performs mitral valve surgery is the unconsciousness of the patient's involvement in the intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.RHC.REC.1397.003

Street address

Valiasr Street. Corner of prayer. Shahid Rajaei Cardiovascular Research Center

City

Tehran

Province

Tehran

Postal code

1741746194

Approval date

2018-04-28, 1397/02/08

Ethics committee reference number

IR.RHC.REC.1397.003

Health conditions studied

1

Description of health condition studied

Miter's disease of the heart

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Duration of admission to the intensive care unit

Timepoint

30 days

Method of measurement

Hospital hours in the intensive care unit

Secondary outcomes

1

Description

Function and respiratory complications

Timepoint

The examination is done prior to the onset of intervention and 30 days of respiratory physiotherapy.

Method of measurement

6 minutes walk and lung radiography

Intervention groups

1

Description

The intervention group performs respiratory physiotherapy with the power brath before the 30-day operation.

Category

Prevention

2**Description**

Control group: The control group receives all necessary measures and care. They do not receive pre-operative physiotherapy.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Rajaee Cardiology Hospital Tehran

Full name of responsible person

Mandana Mashhadi Jafari

Street address

Valiasr Street. The Hospital of Shahid Rajaee Cardiology Tehran

City

Tehran

Province

Tehran

Postal code

1741746194

Phone

+98 21 23921

Email

mandanajafara1348@rhc.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shaheed Rajaee cardiovascular research center

Full name of responsible person

Dr. Majid Maleki

Street address

Valiasr Street, Corner of the Avenue of Prayer

City

TEHRAN

Province

Tehran

Postal code

1741746194

Phone

+98 21 23921

Email

majid33@yahoo.com

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shaheed Rajaee cardiovascular research center

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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**Shahid Rajaee Cardiovascular Research Center
Tehran**Full name of responsible person**

Mandana Mashhadi Jafari

Position

Student Masters Degree

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Valiasr Ave. Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1741746194

Phone

+98 21 23921

Email

mandanajafari1348@rhc.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**Research Center for Therapeutic Therapy for Heart
and Rajaji Teva in Tehran**Full name of responsible person**

Mandana Mashhadi Jafari

Position

Student Master's Degree Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Valiasr Ave. Tehran University of Medical Science

City

Tehran

Province

Tehran

Postal code
1741746194
Phone
+98 21 23921
Email
mandanajafari1348@rhc.ac.ir

Tehran
Postal code
1741746194
Phone
+98 21 23921
Email
mandanajafari1348@rhc.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Research Center for Cardiovascular Research, Rajai
University of Tehran
Full name of responsible person
ماندانا مشهدی جعفری
Position
Student Master's Degree Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Valiasr Street. The City of Rajae Heart Hospital
Tehran
City
Tehran
Province

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable