Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Rajaee Cardiology Center in Tehran, which requires a mitral valve surgery (with / without need for trecospine 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 Surgeonis 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 drainage 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 brathe 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 Haspital Rajaee

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Iran (Islamic Republic of)

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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 ofstay 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 Rajaee 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
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Person responsible for updating data

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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