Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of "early mobilization protocol" after cardiac surgery on rate diaphragmatic muscle strength

Protocol summary

Summary

The aim of this research is to study the effects of early mobilization protocol after open-heart surgery on the strength of the diaphragmatic muscle. This study is a single-blind and single-center clinical trial which is designed to be accomplished in 6 months. The participants are 80 patients who are candidate for open-heart surgery in the age range of 20-65 years old, with LVEF> 30%, no arrhythmia, no known pulmonary disease and no smoking. Patients are randomly assigned to the groups of intervention (early mobilization) and control the day before surgery by simple randomization. The procedure of measuring breathing muscle strength by Power Breath device is taught to the patient. Then the test is done and PImax and Sindex are recorded. After open-heart surgery and ordering of the responsible physician, considering early mobilization contraindications and Stiller safety rules, the “early mobilization protocol” is employed in intervention group. In control group no mobilization is done, but routine physiotherapy including range of motion exercises in supine position and chest physiotherapy is accomplished by a physiotherapist. When the patient completes the criteria of leaving ICU and with the order of their physician measurement of breathing muscle strength is done. Primary outcome of the present study is changes in PImax and Sindex.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016051527908N1**
Registration date: **2017-01-03, 1395/10/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-03, 1395/10/14

Registrant information

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hassan ariyan

Name of organization / entity

Rajaie cardiovascular center Tehran

Country

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of "early mobilization protocol" after cardiac surgery on rate diaphragmatic muscle strength

Public title

Effect of Early mobilization of Diaphragm Muscles strength

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age of participants must be 20-65

years old; The surgery must be elective; The participants must not be so sleepy and agitated (RASS between -2 and +2); The participants must not have cardiac arrhythmia; LVEF >30% Exclusion criteria: Having long-term mechanical ventilation (more than 48 hours); Difficulties in movement after surgery; Cardiac arrest during or after surgery; Disable to communicate because of neurological, visual or auditory disorders; If each contraindication happened in early mobilization (FIO2 >85%, PEEP>15 , severe heart ischemic, uncontrolled cardiac arrhythmia, impermanent blood pressure despite receiving vasopressors, open sternum، LVEF less than 30%) 6- Known case of pulmonary disease (diaphragm disorder, COPD, hemothorax, pleural effusion, etc); History of thoracic surgery.; Smoking.

Age
From **20 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

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran ,Shahid RajaeeCardiovascular Educational,Researching and clinical institute

Street address
Rajaei Cardiovascular Medical and Research Center, Vali-Asr ave., Niayesh Blvd., Tehran, Iran

City
Tehran

Postal code

Approval date
2016-08-06, 1395/05/16

Ethics committee reference number
RHC.AC.IR.REC.1395.21

Health conditions studied

1

Description of health condition studied
coronary heart disease

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease Coronary (artery): atheroma atherosclerosis disease sclerosis

Primary outcomes

1

Description
PIMAX: maximum pressure that patient must overcome it to bring more air into lung. SINDEX: quality criterion for measuring the breathing muscle power which is based on comparison by the amounts of same normal age, gender, height and weight

Timepoint
patient before surgury and afther surgury and both tow group

Method of measurement
Collecting data tools for this study is power breath device which its producer is KS POWER made in England.

Secondary outcomes

1

Description
heart rate

Timepoint
before and during admission in ICU

Method of measurement
monitoring

2

Description
oxygen saturation

Timepoint
before and during admission in ICU

Method of measurement
monitoring

3

Description
blood pressure

Timepoint
before and during admission in ICU

Method of measurement
monitoring

4

Description
number of days admitted to ICU

Timepoint
during admission in ICU
Method of measurement
nursing report

5

Description
number of stages done in early mobilization protocol
Timepoint
during admission in ICU
Method of measurement
observation by researcher

6

Description
respiratory rate
Timepoint
before and during admission in ICU
Method of measurement
monitoring

Intervention groups

1

Description
In intervention group: patient learns how to breathe ,then measurement of diaphragm muscle strength would be done by power breath. After surgery and emitting chip pipe patient deepens on situation (second day after surgery) and doctor's command in first group by considering safety issues, stiller, contraindication for early mobilization by using early mobilization protocol and by physiotherapy assisting are done. At the end measuring diaphragm strength would be done before leaving ICU.
Category
Rehabilitation

2

Description
In control group: patient learns how to breathe ,then measurement of diaphragm muscle strength would be done by power breath. After surgery and extubation based on doctor's command , physiotherapy would be done by physiotherapist help. At the end measuring diaphragm strength would be done before leaving ICU.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran ,Shahid Rajaee Cardiovascular Educational,Researching and clinical institute
Full name of responsible person
Hassan-Ariyan
Street address
Rajaei Cardiovascular Medical and Research Center, Vali-Asr ave., Niayesh Blvd., Tehran, Iran
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Shahid Rajaei Cardiovascular Medical and Research Center, Iran Univ
Full name of responsible person
Dr.Majid Maleki
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Rajaei Cardiovascular Medical and Research Center, Vali-Asr ave., Niayesh Blvd., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Shahid Rajaei Cardiovascular Medical and Research Center, Iran Univ
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty