

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 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 P_{lmax} and S_{index} 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 P_{lmax} and S_{index}.

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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Name of organization / entity

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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 RajaeCardiovascular
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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. SINDEK: 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 surgery and after surgery 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 Rajae Cardiovascular
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Full name of responsible person

Hassan-Ariyan

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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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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