

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The effect of respiratory muscle training on hospital and ICU stay in patients undergoing coronary and valves surgery

Protocol summary

Study aim

the effect of respiratory muscle training on reducing the duration of mechanical ventilation and the length of stay in the hospital and ICU

Design

After the referral, the written consent of the subjects was obtained. The breathing test was done before and after the intervention for patients. intervention: Patients return to the recovery center 7-5 times a week, at least 2 weeks before surgery. For 15- 30 minutes, exercise breathing exercises with 10-60% strength. The maximum individual respiratory rate (Pimax) should be exercised under the supervision of a physician or physiotherapist. At the first session patients were trained regarding the respiratory muscle training which should do at home. After one week patients referred to evaluate and fix the problems which they faced. At the end of two weeks, pimax (maximum respiratory capacity) was measured.

Settings and conduct

Permuted Block randomization method used. Then divided in two groups including muscle training and pulmicort combivent, and control group which received only pulmonary combivent and both groups evaluated by breathing test and SF36 questionnaire after the study.

Participants/Inclusion and exclusion criteria

inclusion criteria: Age over 18 years Patients who are at the risk of postoperative pulmonary complications are on the same list of surgical procedures for switching vessels and valves. exclusion criteria: Age over 70 year respiratory or pulmonary infections lack of cooperation in the practice lung surgery history Cardiovascular instability and exercise induced bronchospasm The use of immunosuppressive drugs 30 days before surgery Spontaneous pneumothorax history

Intervention groups

Patients go to the recovery center 7-5 times a week, at least 2 weeks before surgery. For 15-30 minutes, exercise breathing exercises with 10-60% strength (Pimax)

Main outcome variables

Maximum strength of the respiratory muscles

General information

Reason for update

Acronym

تقویت عضلات تنفسی قبل از جراحی قلب

IRCT registration information

IRCT registration number: **IRCT20180625040234N1**

Registration date: **2018-07-17, 1397/04/26**

Registration timing: **prospective**

Last update: **2018-07-17, 1397/04/26**

Update count: **0**

Registration date

2018-07-17, 1397/04/26

Registrant information

Name

Hossein Ahmadi tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9733

Email address

mahdavi-a@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of respiratory muscle training on hospital and ICU stay in patients undergoing coronary and valves surgery

Public title
The effect of respiratory muscle training on hospital and ICU stay in patients undergoing coronary and valves surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Patients who are at the risk of postoperative pulmonary complications are on the same list of surgical procedures for switching vessels and valves. The study is conducted in the waiting period for surgery and the results will be measured before surgery. The risk group includes patients over 70 years of age and a history of diabetes and history of smoking and pulmonary disease, (COPD), BMI greater than 27, and impaired pulmonary function (FEV1 <80% and FEZ1 / FVC <70%).
Exclusion criteria:
 Age over 70 years respiratory or pulmonary infections lack of cooperation in the practice lung surgery history Cardiovascular instability and exercise induced bronchospasm The use of immunosuppressive drugs 30 days before surgery Spontaneous pneumothorax history

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **190**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals were selected using Permuted Block randomization method. then were divided in two groups including muscle training and pulmicort combivent, and control group which will receive only pulmonary combivent and both groups will be evaluated by breathing test and SF36 questionnaire after the study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of medicine - Tehran university of medical sciences

Street address

Poursina ave., 6th floor, school of Medicine, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

8415683111

Approval date

2018-06-13, 1397/03/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.125

Health conditions studied

1

Description of health condition studied

Mechanical complication of coronary artery bypass and valve

ICD-10 code

T82.2

ICD-10 code description

Mechanical complication of coronary artery bypass graft and biological heart valve graft

Primary outcomes

1

Description

Maximum strength of the respiratory muscles

Timepoint

Before and after breathing exercises

Method of measurement

Using the power breathe device

2

Description

Duration of admission to ECU

Timepoint

Since the transfer to ECU until clearance

Method of measurement

Patient File

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Inspiratory muscle training (IMT) and treated with pulmicort and combivent inhaler. Patients return to the recovery at least 2 weeks before surgery. At the first session patients were trained regarding the respiratory muscle training which should do at home and pimax (maximum respiratory capacity) was measured. After one week patients referred to evaluate and fix the problems which they faced. At the end of two weeks, pimax (maximum respiratory capacity) was measured.

Category

Rehabilitation

2

Description

Control group: pimax (maximum respiratory capacity) was measured and treated with pulmicort and combivent inhaler.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran heart center

Full name of responsible person

Dr.Sepideh Niyazi

Street address

Tehran Heart Center, North Kargar St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

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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

Tehran University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Public

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

Tehran University of Medical Sciences

Full name of responsible person

Sepideh Niyazi

Position

Sport Medicine

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Ahmadi Tafti

Position
CARDIAC SURGEONS
Latest degree
Subspecialist
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Person responsible for updating data

Contact
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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

It is possible to share the information regarding the main consequence .

When the data will become available and for how long

The publication of this research work will start after the end of the year 1399.

To whom data/document is available

Our study data will be available to researchers and all medical doctors and medical students.

Under which criteria data/document could be used

It is authorized to use this scheme for upcoming research works and promoting the patients' treatment.

From where data/document is obtainable

Applicants can visit the doctor Niyazi at Tehran Heart Center

What processes are involved for a request to access data/document

After finishing the work and publishing the article the work can be referred and cited.

Comments