Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 21 8802 9733

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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 inhaller.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 inhaller.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center
Full name of responsible person
Dr.Sepideh Niyazi
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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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Poursina ave., 6th floor, school of Medicine, Tehran University of Medical Sciences
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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
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CARDIAC SURGEONS
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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