

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Survey efficiency of the cardiac rehabilitation program after coronary artery bypass graft on respiratory characteristics.

Protocol summary

Study aim

Determination efficiency of the cardiac rehabilitation program after coronary artery bypass graft on respiratory characteristics in admitted patients to Dr.Heshmat educational and remedial center in Rasht city in 2018.

Design

A Clinical trial with 2 groups control and case, parallel, no blinding and randomized . with sample size: 54 patients

Settings and conduct

In the first group "rehabilitation with incentive spirometry like routine (control)" and the second group "receive CPAP with mask 4-6 cmH2o until 35 minutes (case)" besides routine. After 2 hours, progressive exercises as walking start on the first day, 5-10 minutes (base on patients tolerance), in the second day 10-15 minutes and in the third day 15 minutes and more. At the end of each session, all of the patients will evaluate with modified Borg scale CR-10 for dyspnea and RPE scale for leg effort. In the fourth day, the final results will evaluate with spirometry parameters. Location of sampling: heart surgery ward in Dr.Heshmat hospital, Rasht.

Participants/Inclusion and exclusion criteria

Inclusion criteria : No Emergency Operation. Patients with elective CABG. Nonuse of the intra-aortic balloon pump. The patient's ability to perform the exercise. Nonexistence of valvular heart disease and chronic obstructive pulmonary disease. Nonexistence of acute respiratory problems. Nonexistence of Af. Exclusion criteria : Unstable angina. Dysrhythmia. Patient intolerance CPAP.

Intervention groups

The first group: patients receive incentive spirometry like routine rehabilitation(control) and the second group: receive CPAP with mask 4-6 cmH2o until 35 minutes (case) besides routine.

Main outcome variables

Dyspnea Spo2 Leg effort Spirometry parameters:

General information

Reason for update

Acronym

GUMS

IRCT registration information

IRCT registration number: **IRCT20101019004971N5**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

Registration date

2018-07-22, 1397/04/31

Registrant information

Name

Mohamadtaghi Moghadabnia

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 2088

Email address

moghadamnia@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-05, 1397/03/15

Expected recruitment end date

2018-12-06, 1397/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey efficiency of the cardiac rehabilitation program after coronary artery bypass graft on respiratory characteristics.

Public title

Survey efficiency of cardiac rehabilitation program after coronary artery bypass graft on respiratory characteristics

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

No Emergency Operation No CABG history in the past clinical diagnosis of coronary artery disease, who underwent elective coronary Artery bypass graft (CABG) with cardiopulmonary bypass, a median sternotomy incision and use of a saphenous vein, internal thoracic artery, or radial artery grafts No use of intra-aortic balloon pump No use of permanent pacemaker Ability to perform exercise according to our protocol No valvular heart disease, chronic obstructive pulmonary disease No respiratory problems that cause to add length of intensive care unit stay No Atrial fibrillation arrhythmia and use of Amiodarone protocol

Exclusion criteria:

Unstable angina chronic disturbances in heart rhythm significant acute arrhythmias Do not tolerate Continuous Positive Airway Pressure (CPAP) with patient

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **54**

More than 1 sample in each individual

Number of samples in each individual: **1**

Every participant stand in case or control group by randomization

Randomization (investigator's opinion)

Randomized

Randomization description

randomized a block size of 2

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

samples dispart into two groups (control and case) : first group receive incentive spirometry like routine rehabilitation and second group receive CPAP with mask 4-6 cmH2o until 35 minute (the first 5 minute allocate to reduce stress and adaptation with this device) beside incentive spirometry . after 2 hours , progressive exercises as walking start in the first day, 5-10 minutes

(base on patients tolerance) , in the second day 10-15 minutes and in the third day 15 minutes and more . at the end of each cession all of the patients will evaluate with modified Borg scale CR-10 for dyspnea and RPE scale for leg effort . In the forth day the final results will evaluate with spirometry parameters .

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Guilan University of Medical Sciences

Street address

Deputy of Research and Technology of Guilan University of Medical Sciences ., across 17 shahrivar hospital., shahid Siadati Ave., Namju Blvd., Rasht

City

Rasht

Province

Guilan

Postal code

4144665385

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.GUMS.REC.1397.007

Health conditions studied**1****Description of health condition studied**

efficiency of cardiac rehabilitation program after coronary artery bypass graft on respiratory characteristics

ICD-10 code

I25

ICD-10 code description

Chronic ischemic heart disease

Primary outcomes**1****Description**

Dyspnea in patients who reveived score above 5 in Modified Category Ratio-10 (CR-10)

Timepoint

At the end of the first to third sessions after intervention

Method of measurement

Scoring in Modified Category Ratio-10 (CR-10)

2

Description

Leg effort in patients who received score above 15 in Rate of Perceived Exertion (RPE- Scale).

Timepoint

At the end of the first to third sessions after intervention

Method of measurement

Scoring in Rate of Perceived Exertion (RPE- Scale)

Secondary outcomes

1

Description

Spirometry parameters changes

Timepoint

In the forth session

Method of measurement

Spirometry

Intervention groups

1

Description

Intervention group: In this group patients besides receiving routine incentive spirometry in their cardiac rehabilitation program use Continuous Positive Airway Pressure mask (CPAP) till 35 minutes, due to patients tolerance before walking (the first 5 minutes related to reduce stress and adaptation) . In the first day, exercises start as walking (due to patients tolerance) 5-10 minutes , in the second day 10-15 ,and in the third day 15 minutes and more after 2 hours pass from using CPAP.

Category

Rehabilitation

2

Description

Control group: In this group patients receive incentive spirometry and deep breathing exercises for 30 minutes and then exercises start as walking (due to patients tolerance) 5-10 minutes , in the second day 10-15 ,and in the third day 15 minutes and more after 2 hours pass from using incentive spirometry .

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Heshmat hospital

Full name of responsible person

Mohammad Taghi Moghadamnia

Street address

Bayani alley., Mosala Blvd., Dr.Heshmat hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Taghi Moghadamnia

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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

Rasht University of Medical Sciences

Proportion provided by this source

100

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

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Taghi Moghadamnia

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

No, 1, Havashenasi Ave, Moalem Blvd, Rasht, Iran

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Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Health in Emergency and Disaster

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Taghi Moghadamnia

Position

Assistant Professor of Rasht university of medical

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

Undecided - It is not yet known if there will be 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

Only a portion of the data about the outcome of interventions. will be shared. Personal information will not be absolutely shared.

When the data will become available and for how long

The Six Months after publish of results

To whom data/document is available

University Researchers

Under which criteria data/document could be used

With formal request and Announcing the source of the data and Permission from researchers use of is allowed.

From where data/document is obtainable

Email to the moderator of the project, Mohammad Taghi Moghaddam Nia Moghadamnia@gums.ac.ir

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

After contacting to the email of moderator of project, the request will be reviewed and answered within 3 business days.

Comments