Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 intolerancy 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

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Mohamadtaghi Moghadabnia

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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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 fibrilation arrhythmia and use of Amiodarone protocle

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 spirometery 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 shahahrivar hospital., shahid Siadati Ave., Namju Blvd., Rasht

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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 reveived 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
Spirometery parameters changes
Timepoint
In the forth session
Method of measurement
Spirometery

Intervention groups

1

Description
Intervention group: In this group patients besides receiving routine incentive spirometery 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 spirometery 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 spirometery .
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Postal code
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Email
Moghadamnia@gums.ac.ir
Web page address

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 dataabout 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 reviwe and answered within 3 business days.
Comments