Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of different exercise regimens of the first phase of cardiac rehabilitation on the discharge day performance of open heart surgery patients

Protocol summary

Study aim
Investigating the effect of different exercise regimens of the first phase of cardiac rehabilitation on the discharge day performance of open heart surgery patients

Design
Clinical trial with a control group, with parallel groups, single-blind, randomized, on 32 patients.Simple randomization was used.

Settings and conduct
This study will be conducted in Erfan Niayesh Hospital.First, teaching patients about the effects of surgery on cardiopulmonary function, general cases after surgery one day before surgery and the cardiac rehabilitation program, which generally includes mobilization of the patient as soon as possible, teaching breathing exercises, personal care will be given from the day before the surgery to discharge.The patient and the therapist know the study groups and only the evaluator (examiner) is blind.before surgery and discharge day, spirometry and 6-minute walking test were taken by an evaluator.

Participants/Inclusion and exclusion criteria
People who candidates for open heart surgery (coronary artery bypass graft, valve replacement, or both) based on: - Age over 18 years and less than 70 years - Independent walking - No history of surgery in the past - Non-emergency surgery - No history of recent myocardial infarction (past 6 months) - Not having a pacemaker - Not having chronic obstructive pulmonary disease - Absence of severe non-cardiac disease

Intervention groups
The cardiac rehabilitation program, which generally includes: mobilization of the patient as soon as possible, teaching breathing exercises and personal care, once or twice daily (one group, once and the other group twice a day), from the day before the operation until the day of discharge will be given.

Main outcome variables
distance walked in six minute walk tes؛ forced vital capacity ؛Forced expiratory volume in first second؛forced expiratory volume in first second/forced vital capacity ratio

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230527058305N1**
Registration date: **2023-06-21, 1402/03/31**
Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**
Update count: **0**

Registration date
2023-06-21, 1402/03/31

Registrant information

Name
Oweis Rezaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4979 6260

Email address
oweisrezaei@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-25, 1402/04/04

Expected recruitment end date
2023-07-28, 1402/05/06

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of different exercise regimens of the first phase of cardiac rehabilitation on the discharge day performance of open heart surgery patients

Public title
Investigating the effect of different exercise regimens of the first phase of cardiac rehabilitation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Open heart surgery(coronary artery bypass graft,valve replacement or both) candidate patients
Exclusion criteria:
History of open heart surgery Emergency surgery History of recent myocardial infarction (past 6 months) Implanted pace maker Having chronic obstructive pulmonary disease Severe non-cardiac disease
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method was used to select people in these two groups. From the beginning, it was agreed that intervention group 1 would be given odd numbers and intervention group 2 would be given even numbers. Then, according to the number of sample size (32) under study, the relevant random numbers were extracted using Excel software, and each number was written on a card and placed in an envelope, and the envelopes were sealed, and on each envelope was the patient's number.Envelope number 1 will be given to the first patient who is enrolled in the study, envelope number 2 will be given to second patient , and so on.until the end of the study sample.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study patients and therapist know the situation of patients in groups.only assessor do not know the situation of patients in groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of University of Social Welfare and Rehabilitation sciences
Street address
Kodakyaar Deadend., Daneshjoo Blvd.,Evin.,Tehran
City
Tehran
Province
Tehran
Postal code
1985713834
Approval date
2023-06-14, 1402/03/24
Ethics committee reference number
IR.USWR.REC.1402.047

Health conditions studied

1

Description of health condition studied
Chronic ischemic heart disease
ICD-10 code
I25
ICD-10 code description
Chronic ischemic heart disease

2

Description of health condition studied
Rheumatic mitral valve diseases
ICD-10 code
I05
ICD-10 code description
Rheumatic mitral valve diseases

3

Description of health condition studied
Nonrheumatic mitral valve disorders
ICD-10 code
I34
ICD-10 code description
Nonrheumatic mitral valve disorders

4

Description of health condition studied
Multiple valve diseases
ICD-10 code
I08

ICD-10 code description
Multiple valve diseases

5

Description of health condition studied
Rheumatic aortic valve diseases
ICD-10 code
I06
ICD-10 code description
Rheumatic aortic valve diseases

6

Description of health condition studied
Nonrheumatic aortic valve disorders
ICD-10 code
I35
ICD-10 code description
Nonrheumatic aortic valve disorders

Primary outcomes

1

Description
distance walk in six minute walk test
Timepoint
Before intervention (surgery) and discharge day
Method of measurement
In this test we want from patient to walk as far as he or she can in six minute . Patient will walk in a 30 meter path up and down. There are some chairs through the path for rest.patient allowed to rest in case of fatigue or symptoms like chest pain, shortness of breath or musculoskeletal pain.the patient continues to walk until the time of six minutes is over.

2

Description
Forced vital capacity
Timepoint
Before intervention (surgery) and discharge day
Method of measurement
With spirometer (spirolab MIR company)

3

Description
Forced expiratory volume in first second
Timepoint
Before intervention (surgery) and discharge day
Method of measurement
With spirometer (spirolab MIR company)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:cardiac rehabilitation program, which generally includes: early mobilization of the patient as soon as possible, teaching breathing exercises and organs, teaching personal care, will be given in the number of one session per day, from the day before the operation to the day of discharge.
Category
Rehabilitation

2

Description
Intervention group:cardiac rehabilitation program, which generally includes: early mobilization of the patient as soon as possible, teaching breathing exercises and organs, teaching personal care, will be given in the number of two session per day, from the day before the operation to the day of discharge.(The difference between this group and intervention group 1 is in the frequency of therapeutic sessions, which is twice a day).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Erfan niayesh hospital
Full name of responsible person
Oweis Rezaei
Street address
No 17 , Bahar St , Kabiri taame Blvd, Central jannat abad , West Hemmat Exp,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Hamidreza Khanke
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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences
Full name of responsible person
Oweis Rezaei
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be 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
No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the data related to the demographic information of the patients and their related medical documents and the test results of this research can be shared.

When the data will become available and for how long

The access period starts after the article is published in the journal

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Research uses for articles in the medical field

From where data/document is obtainable

1. Oweis Rezaei at the email address oweisrezaei@gmail.com at the phone number 0098 939 374 6002 2. Dr. Farhad Azadi at the email address fa_azadi@yahoo.com

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

First, the request is sent by the applicant to the email address of the mentioned people. Then, if the main researcher approves and after reviewing the applicant's documents, the requested data will be sent as a file

Comments