

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Phase I Cardiac Rehabilitation on the Rate of Delirium in Patients After Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim

Influence of phase one cardiac rehabilitation on delirium after coronary artery bypass graft surgery

Design

This study is a randomized clinical trial with two groups of intervention and control. The sample size is 30 patients for the intervention group and 30 patients for the control group. Statistical analysis was performed using SPSS software version 20.

Settings and conduct

This study was performed on patients admitted to the open heart surgery intensive care unit and open heart surgery ward of Imam Reza Hospital in Imam Reza Square who undergo coronary artery bypass surgery.

Participants/Inclusion and exclusion criteria

1. over 18 years of age 2. lack of history of heart surgery 3. no history of known medical illness based on medical records 4. no motor impairment that prevents walking 5. no history of delirium 6. no use of medications Preoperative psychiatric and sedative 7. Having a RASS score of zero means that the patient is alert and can cooperate with the researcher.

Intervention groups

Phase one cardiac rehabilitation, two to three times a day for 20 to 30 minutes at a time, according to the Ministry of Health guidelines, which consists of three parts: 1. Respiratory exercise training and control by the researcher; 2. Discussion with the patient; 3. The patient was encouraged to perform activities for the intervention group. The control group received routine care.

Main outcome variables

Incidence and severity of delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191224045878N1**

Registration date: **2020-02-19, 1398/11/30**

Registration timing: **retrospective**

Last update: **2020-02-19, 1398/11/30**

Update count: **0**

Registration date

2020-02-19, 1398/11/30

Registrant information

Name

kolsoom parnan emamverdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2019-12-21, 1398/09/30

Scientific title

The effect of Phase I Cardiac Rehabilitation on the Rate of Delirium in Patients After Coronary Artery Bypass Graft Surgery

Public title

The effect of Phase I Rehabilitation on the Delirium in

Cardiac Surgery Patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Be in a Group over the 18 Years Do not use the Psychiatric or Antirelaxant Medications Do not have a History of Heart Surgery Do not have a Movement Problem Do not have a History of Delirium Having a Score 0 From RASS means the patients is calm and relax and able to cooperative with researcher Do not have a Known psychiatric Disease
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**
 Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
 In this Research, Inclusion of research units in the Study, The Method is Available and Random Allocation. Random Sequence Tool is SPSS. Random Sequence Was Prepared as a Table. It was Kept in an envelope. After making sure everyone is eligible, Envelope door Opened And The Sequence was assigned to that Group

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Intersection Doctorate, Ibn Sina St, Mashhad

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Province

Razavi Khorasan

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9137913199

Approval date

2019-10-25, 1398/08/03

Ethics committee reference number

IR.MUMS.REC.1398.156

Health conditions studied

1

Description of health condition studied

Coronary Artery Bypass Graft

ICD-10 code

F05.8

ICD-10 code description

Postoperative Delirium

Primary outcomes

1

Description

Delirium

Timepoint

Since the End of the Endotracheal Tube Up to 5 to 7 days after Surgery

Method of measurement

Neecham Tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Individuals find the phase of a cardiac rehabilitation based on a Ministry of Health instruction that consists of three parts, including: 1. Exercise training and control by the researcher; 2. Discussion with the patient; 3. The patient was encouraged to perform activities for the intervention group. Exercise should be performed two to three times a day for at least 20 minutes and a maximum of 30 minutes. Then, according to the protocol of the Ministry of Health for 15 to 20 minutes, chest physiotherapy was performed. After chest physiotherapy, depending on whether the patient was in a supine position, sitting or standing, appropriate exercises were performed for the patient. At each exercise session, about 5 to 10 minutes to warm up, 5 to 10 minutes to cool and 20 to 30 minutes to exercise. Chest physiotherapy was given 15 to 20 minutes per session. In addition, diaphragmatic breathing training was performed face-to-face with the aid of image and shape, and the subjects performed exercise at least once a day in the presence of the researcher, and the next time, the patient performed the exercise alone. And to control gestures, the researcher was assisted in various shifts to monitor her performance as well as the accuracy of the exercise. In step two, the benefits of the cause and the disadvantages and overall

self-care were described to the patient. Possible questions and uncertainties about surgery, diet, medications, post-operative rest, risk factors control, time to start daily activities, and marital relationships were answered and the patient was asked about any concerns and concerns. The researcher points out. In step three, the patient was used to encourage verbal communication and positive feedback to him and his family, such as good, effective, excellent in the presence of the patient. This rehabilitation started from the end of the endotracheal tube and continued for 5 to 7 days until the end of the open heart session. The control group received routine nursing interventions in the ward and in both the control and intervention groups, the scale (Nicham) was completed, measured and compared daily to assess the incidence of delirium at the same time.

Category

Rehabilitation

2

Description

Control group: In addition to receiving routine care, at the end of two weeks, a control booklet was administered to patients in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Open heart surgery intensive care unit and open heart surgery unit in Imam Reza hospital in Mashhad

Full name of responsible person

Akram Kiani

Street address

Imam Reza Hospital, Shariati Square, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Kolsoom Parnan Emamverdi

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Kolsoom Parnan Emaverdi

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

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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

Presentation of research findings in seminars, conferences, and publication of articles extracted from research in domestic and overseas journals, all hospitals, and even other departments, especially after surgical operations requiring the use of specific medications following psychologic complications. Have surgery, be used As well as researchers who intend to conduct research on the subject.

When the data will become available and for how long

Start of course available 6 months after printing results

To whom data/document is available

Share the results of the research with other researchers for further research

Under which criteria data/document could be used

Used in all hospitals and even in other wards, especially after surgeries that require the use of specific medications in the aftermath of psychologically induced complications.

From where data/document is obtainable

Visit to Mashhad School of Nursing and Midwifery

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

After the email is sent to the scientific respondent, the accountability process begins

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

Mashhad University of Medical Sciences

Full name of responsible person

Kolsoom Parnan Emamverdi

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

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