Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of an Early Mobilization program on Functional capacity, Kinesiophobia and Quality of Recovery in patients undergoing Coronary Artery Bypass Graft surgery

Protocol summary

Study aim

To determine the effect of an early mobilization program on functional capacity, kinesiophobia, and quality of recovery in patients after coronary artery bypass graft surgery

Design

A single-blind randomized controlled clinical trial with two parallel groups conducted on 60 patients, randomized using Random Allocation software.

Settings and conduct

Sampling will be conducted at Fatemeh Zahra Hospital using a convenience sampling method. Patients will be allocated to the intervention and control groups using Random Allocation software with randomly sized blocks. Interventions will begin 24 hours after surgery and will continue until discharge. Outcomes will be assessed by blinded evaluator who will access only patient ID codes and will be unaware of group assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Undergoing CABG, age 18 - 70 years, completion of the informed consent form, ability to follow the researcher’s instructions Exclusion criteria: History of previous cardiac surgery, history of performing the 6MWT, LVEF<35%, patient being CBR before surgery, need for emergency surgery, presence of known pulmonary disease, movement disorders and neurological problems, severe visual or hearing impairment and inability to communicate, renal failure, Duration of cardiac surgery > 6 hours, GCS <15 24 hours after surgery, Mechanical ventilation time > 24 hours

Intervention groups

Intervention: This group, in addition to standard care and routine physiotherapy, will undergo an early mobilization program twice daily from 24 hours after surgery until discharge. The program includes ROM exercises, sitting in bed and at the bedside, walking with gradual distance progression, and climbing stairs. Control: This group will receive only standard care and routine physiotherapy on a daily basis.

Main outcome variables

Functional capacity; Kinesiophobia; Quality of recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151004024342N9**
Registration date: **2025-11-14, 1404/08/23**
Registration timing: **prospective**

Last update: **2025-11-14, 1404/08/23**
Update count: **0**

Registration date

2025-11-14, 1404/08/23

Registrant information

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2026-06-21, 1405/03/31

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

Scientific title
The effect of an Early Mobilization program on Functional capacity, Kinesiophobia and Quality of Recovery in patients undergoing Coronary Artery Bypass Graft surgery

Public title
Effect of Early Mobilization after Coronary Artery Bypass Graft surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Undergoing coronary artery bypass graft (CABG) surgery Age between 18 and 70 years Completion of the informed consent form Ability to follow the researcher’s instructions
Exclusion criteria:
History of previous cardiac surgery History of performing the 6-minute walk test (6MWT) Left ventricular ejection fraction (LVEF) less than 35% Patient being CBR before surgery Presence of known pulmonary disease (chronic obstructive pulmonary disease (COPD), severe refractory asthma, or respiratory failure) presence of movement disorders (limb amputation, balance or gait disturbance, limb weakness, rheumatoid arthritis, or other severe joint diseases severely limiting movement) Presence of neurological problems (uncontrolled epilepsy or neurodegenerative diseases such as Parkinson’s disease or multiple sclerosis) Severe visual or hearing impairment and inability to communicate Renal failure Need for emergency surgery Duration of cardiac surgery more than 6 hours Low level of consciousness (GCS <15) 24 hours after surgery Mechanical ventilation lasting more than 24 hours
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: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed at the individual level using block randomization. After selecting eligible patients through convenience sampling, the random allocation sequence will be generated using the Random Allocation software. The number and size of the blocks will also be determined randomly by the software, based on multiples of 4, 6, and 8.The final randomization list will be prepared before the start of the study, and patients will be allocated to the intervention or control group according to their order of enrollment and in accordance with this sequence.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the intervention, it is not possible to blind the participants and the therapist; however, the assessor responsible for measuring the study outcomes, including functional capacity, kinesiophobia, and quality of recovery, will be blinded and will have no knowledge of the group allocation of the patients.
Placebo
Not used
Assignment
Parallel
Other design features
Post-randomization withdrawal criteria: Hemodynamic instability (requiring simultaneous use of more than one type of inotropic drug, use of intra-aortic balloon pump (IABP), or presence of second- or third-degree AV block), need for reoperation, unstable angina after surgery, cardiac arrest after surgery, unwillingness to continue participation, transfer to another hospital, death of the patient

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Building No. 2, Vice Chancellor for Research, Mazandaran University of Medical Sciences, Moallem Square
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Postal code
4816715793
Approval date
2025-10-29, 1404/08/07
Ethics committee reference number
IR.MAZUMS.REC.1404.425

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft (CABG)
ICD-10 code

T82

ICD-10 code description

Complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description

Functional capacity

Timepoint

ChatGPT said:The assessment of functional capacity will be performed in the first stage one day before surgery, prior to the start of the intervention, and in the second stage on the day of hospital discharge.

Method of measurement

6-minute walk test

Secondary outcomes

1

Description

Kinesiophobia

Timepoint

The level of kinesiophobia will be assessed at four time points: 24 hours after surgery (before the start of the intervention), on the third and fifth postoperative days, and on the day of hospital discharge.

Method of measurement

Kinesiophobia will be assessed using the Tampa Scale for Kinesiophobia (TSK).

2

Description

Quality of recovery

Timepoint

The quality of recovery will be assessed at two time points: 24 hours after surgery (before the start of the intervention) and on the day of hospital discharge.

Method of measurement

The quality of recovery will be assessed using the 40-item Quality of Recovery questionnaire (QoR-40).

Intervention groups

1

Description

Intervention group: Patients in the intervention group, in addition to receiving standard hospital care and routine physiotherapy (including respiratory physiotherapy, limb physiotherapy, incentive spirometry, and use of a vibrator), will participate in an early mobilization program twice daily (morning and evening) from 24 hours after surgery until discharge. On the first day, patients will perform passive range of motion exercises for both upper and lower limbs (8–10 repetitions for each movement) and will sit on the bed for 15 minutes during each session. On the second day, patients will perform active range of motion exercises and sit at the edge of the bed with legs dangling for 10 minutes during each session. On the third day, in addition to the previous activities, after disconnecting monitoring lines and clamping the drains, patients—while being monitored with a portable pulse oximeter and supported by the researcher—will sit on a chair beside the bed for 15 minutes, and if their heart rate and respiratory status are stable, they will walk 20–50 meters beside the bed. On the fourth day, under similar conditions, patients will walk 50–100 meters with the researcher's support. On the fifth day, patients will walk 100–200 meters independently under the researcher's supervision and will also climb 3–5 stairs with support. From the sixth day until discharge, patients will, according to their tolerance, increase the walking distance and the number of stairs climbed during each session. Each intervention session will last an average of 30 minutes. Before starting each session, vital signs and pain level will be assessed using the Visual Analogue Scale (VAS) and recorded in the daily intervention checklist. If the patient reports a pain intensity of 4 or higher on the VAS, the researcher will request an analgesic prescription from the physician. After the medication is administered, a waiting period corresponding to the onset of action or, if necessary, half-life duration (based on the pharmacological characteristics of the drug) will be observed. Subsequently, the pain intensity will be reassessed, and if it decreases to below 4, the exercise session will begin. The type, dosage, and frequency of analgesic use, along with the reported pain intensity, will be documented for comparison between groups. The exercise intensity during all sessions will be maintained between 11 and 13 on the Borg Rating of Perceived Exertion (RPE) scale (6–20), corresponding to a light to somewhat hard level of effort. During mobilization out of bed, patients will be monitored using a portable pulse oximeter. If the heart rate increases by more than 20% from baseline or if the oxygen saturation (SpO_2) drops below 90%, the intervention will be terminated for that session.

Category

Rehabilitation

2

Description

Control group: Patients in the control group will receive standard hospital care and routine physiotherapy (including respiratory physiotherapy, limb physiotherapy, incentive spirometry, and the use of a vibrator) once daily from the first working day after surgery until hospital discharge. During their stay in the ICU-OH, these patients will not receive any structured or systematic exercise program for gradual mobilization, and getting out of bed will begin only after their transfer to the ward.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemeh Zahra Hospital

Full name of responsible person
Hessameddin Sharifnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
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Position
Phd.Educational Nursing-faculty member

Latest degree
Ph.D.

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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