Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Aug 2026

Comparison of the Effect of two Early Mobilization Protocols on Pain severity, Aterial Oxygen Saturation, Hemodynamics Parameters, Postoperative Complications in Patients Undergoing Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim
Determining the effect of two Early Mobilization Protocols on pain severity, changes in Hemodynamic parameters, changes in mean Arterial Blood Oxygen level, Postoperative Complications in patients undergoing CABG

Design
The present study is a single-blind randomized clinical trial with a parallel three-arm design. Eligible available samples will be randomly assigned to a control group and two intervention groups with a 1: 1: 1 ratio. Random allocation sequences will be generated by the non-research person using RAS (Random Allocation Software) and random blocking using 3 and 6 blocks for allocation in three groups..

Settings and conduct
Eligible individuals will be admitted to the ICU of Shahid Madani Hospital in Tabriz after CABG, and then will participate in this study for the early Mobilization protocol intervention groups and for the control group of routine measures and their satisfaction. In this study, blinding is done using a matte, closed and uniform envelope, which is numbered from one end to the other.

Participants/Inclusion and exclusion criteria
Age over 18 years; Stable Hemodynamics; Absence of Motor, Auditory and visual problems; Lack of Respiratory distress

Intervention groups
In this study, we will have three groups, including two intervention groups and a control group. In the control group, routine care measures will be performed early in the ward. For the first intervention group, the protocol (Early Progressive Mobilization) based on the Morris which will be implemented in 6 steps twice a day until the fifth day. The protocol of the second intervention group with emphasis on strengthening exercises of respiratory muscles and early Mobolization is designed by Ayshegul yayla, which is performed from day 0 to 5.

Main outcome variables
Pain severity; Hemodynamics parameters; Aterial oxygen saturation; Postoperative complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160110025937N7**
Registration date: **2022-05-25, 1401/03/04**
Registration timing: **prospective**

Last update: **2022-05-25, 1401/03/04**
Update count: **0**

Registration date
2022-05-25, 1401/03/04

Registrant information

Name
Aefeh Allahbakhshian

Name of organization / entity
Tabriz 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

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of two Early Mobilization Protocols on Pain severity, Aterial Oxygen Saturation, Hemodynamics Parameters, Postoperative Complications in Patients Undergoing Coronary Artery Bypass Graft Surgery

Public title

Comparison of the Effect of two Early Mobilization Protocols on Pain severity, Aterial Oxygen Saturation, Hemodynamics Parameters, Postoperative Complications in Patients Undergoing Coronary Artery Bypass Graft Surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Stable Hemodynamics Absence of Motor, Auditory and Visual Problems Lack of Respiratory Distress

Exclusion criteria:

Open Sternum Uncontrollable Dysrhythmia Cardiac Arrest during Surgery and after Admission to the ICU Mechanical Ventilation Duration more than 24 hours

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible available samples will be randomly assigned to the control group, The First Intervention group, and the Second Intervention group by assigning a 1: 1: 1 ratio. Random Allocation Sequences will be generated by the non-research person using RAS (Random Allocation Software) Software and Random Blocking will be generated using 3 and 6 blocks for Allocation in three groups (two intervention groups and one control group). The allocation concealment will be done based on the generated sequence using opaque, closed and uniform envelopes numbered from number 1 to the end. The first person to enter the study will be given envelope number 1 and this process will continue until the end.

Blinding (investigator's opinion)

Single blinded

Blinding description

The allocation hiding will be done based on the generated sequence using opaque, closed, and uniformly envelopes numbered from number 1 to the end. The first person to enter the study will be given envelope number 1 and this process will continue until the end. Therefore, the researcher and the subject will not have any information about the type of allocation received until the envelopes are opened. In this study, they will be a statistical analyzer and examine the outcome of the course

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz, Golgasht St., Tabriz University of Medical Sciences, Central Building No. 2, 3rd Floor

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Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.TBZMED.REC.1401.163

Health conditions studied

1

Description of health condition studied

chronic ischemic heart disease

ICD-10 code

I25.82

ICD-10 code description

Chronic total occlusion of coronary artery

Primary outcomes

1

Description

Pain severity

Timepoint
Before Intervention, Immediately after Intervention, 15 minutes after Intervention
Method of measurement
Visual Analogue Scale

2

Description
Aterial Oxygen Saturation
Timepoint
Before intervention, After intervention
Method of measurement
Using Pulse Oximetry

3

Description
Hemodynamics Parameters
Timepoint
Before Intervention, Immediately after Intervention, 15 minutes after Intervention
Method of measurement
Monitoring device

4

Description
postoperative Complications
Timepoint
Before intervention, After intervention
Method of measurement
Using Chest X Ray and Doctor Visits

Secondary outcomes

1

Description
Length of Hospital Stay
Timepoint
On the day of discharge from the hospital
Method of measurement
By calculating the number of days hospitalized

Intervention groups

1

Description
Intervention group: The intervention group includes progressive early mobilization based on the Morris protocol and modified by Azarafarin et al. Which will be performed in 6 stages: patients after surgery and admission to the intensive care unit according to the level of consciousness of patients based on coma criteria. Glasgow in case of full consciousness, ie GCS = 15 and according to inclusion and exclusion criteria for intervention, if eligible to perform the intervention, 6-8 hours after removal of the patient's endotracheal tube, which is installed for mechanical ventilation. And within 24 hours after surgery, early movement will be performed for the patientBefore performing the intervention, the patient will be evaluated using the mentioned instruments in terms of pain intensity, hemodynamic indicators, postoperative complications (pulmonary complications, deep vein thrombosis) and arterial blood oxygenation level using the mentioned instruments. And then this protocol will be implemented for the first intervention group. This protocol consists of 6 stages that are progressively monitored based on the patient's tolerance level and by the early movement team which includes a heart surgeon, anesthesiologist, nurse, physiotherapist, assistant nurse, twice a day at 10 am, 5 pm and 5 pm. The consecutive day will be performed from the first day after surgery (24 hours after surgery) and up to four days after that, ie the fifth day after surgery:1- The movements start from changing the position in the bed and then the head is raised 45 degrees. 2- The ROM movements are performed for the upper and lower limbs for 5 minutes. 3- The patient sits in the bed for 5 minutes with the help and support of the researcher. If the previous stage is tolerated, the patient will be placed on the edge of the bed with hanging legs for 5 minutes. 5. Based on the tolerance level, the patient is placed standing next to the bed for 5 minutes and then transferred to a chair next to the bed and placed in this position for 5 minutes. 6- In the last stage, the patient travels a distance for 6 minutes with the help of a nurse and with pulse oximetry and by controlling heart rate indicators and SPO2 and patient tolerance level and with confidence in connections and drainage pipes
Category
Rehabilitation

2

Description
Intervention group: This protocol includes early mobilization and ocular strengthening exercises designed by Ayshegul yayla. This protocol is also performed by the early movement team, which includes a heart surgeon, anesthesiologist, nurse, physiotherapist, and nurse assistant, in the first 5 days after the operation, so that steps of this protocol are performed every day and go to The next few days the protocol will be more complete. The day operation protocol is 4 steps and the rest of the days are 5 steps. This protocol will be implemented twice at 11 am and 6 pm. Patients from surgery and admission to the surgical intensive care unit according to the level of consciousness of patients with Glasgow coma criterion in case of full consciousness, ie GCS = 15 and inclusion of inclusion and exclusion criteria for intervention.If eligible for the intervention, 6-8 hours after removal of the patient's endotracheal tube, which was installed for mechanical ventilation, the pre-test is performed as in the previous intervention and the intervention is performed. Thus: On the day of operation (day zero): 8 hours after the exit of the endotracheal tube is raised 30 to 45 degrees and encouraging spirometry, deep breathing exercises and cough eight times a day (twice a day, 4 sets each time) it is possible. Then, inactive limb exercises are performed twice a day for 5 sets each time for 10 minutes based on patient

tolerance. Finally, patients sit by the bed twice a day for 15 minutes each time. The first day after surgery or 24 hours after surgery: The head is still 30 to 45 degrees high and encouraging spirometry and effective breathing exercises and coughing are performed twice a day and 4 sets each time.In the third stage, inactive exercises twice a day and 5 sets each time for 10 minutes based on the patient's tolerance level. 4- The patient sits in a bedside chair twice a day for 20 minutes each time. He walks 150 steps. The second day after the operation: up to stage 4, like the first day after the operation, then in the last stage, the patient walks 250 steps in the ward twice a day. Day 3 after the operation: the first, second and third stages, like the previous days, run In the fourth stage, the patient sits on a chair twice a day for 30 minutes instead of 20 minutes and then walks four hundred steps twice a day. The fourth day after the operation: All three stages are performed as in the previous days and in the fourth stage The patient sits on a chair for 45 minutes twice a day and finally walks 400 steps in the ward twice a day.

Category

Rehabilitation

3

Description

Control group: For the control group, routine measures will be performed to perform early movement. Routine measures for early movement in the intensive care unit of cardiac surgery of Shahid Madani Hospital in Tabriz during the inquiry of nurses working in these wards are as follows: After complete orientation of patients and removal of the patient's endotracheal tube 24 hours after surgery under the supervision of a nurse and Accompanied by the patient's nurse, he first hangs his legs from the bed for 5 minutes and then, if the patient tolerates, gets out of bed and travels a tolerable distance, and this is done twice a day until the discharge from the ICU.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Dr Atefe Allahbakhshian

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Sponsors / Funding sources

1

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Atefe Allahbakhshian

Position

PhD in Nursing / Associate Professor

Latest degree

Ph.D.

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
The information requested by the researchers for statistical analysis of the submitted proposal (meta-analysis) will be provided to them
When the data will become available and for how long
Starting access immediately after publication
To whom data/document is available
Data will be available to researchers as well as to journals
Under which criteria data/document could be used
The data will be available to researchers upon request and submission of a meta-analysis proposal using IPD data after individuals have been identified. It will also be made available to journals exclusively for exceptional data checking.
From where data/document is obtainable
Refer to allahbakhshiana@tbzmed.ac.ir
What processes are involved for a request to access data/document
Requests will be emailed and data will be available within a week.
Comments