

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of The effect of early mobilization protocol at three and four phase on clinical outcome in patients undergoing coronary artery bypass graft:a single blinded randomized clinical trial

Protocol summary

Study aim

The effect of three and four phase early movement protocol on clinical outcomes in patients undergoing CABG

Design

This study is a single-blind randomized controlled trial with a parallel three-arm design. After obtaining the permission of the Ethics Committee and the study registration at the Iranian Registry of Clinical Trials, the eligible samples will be randomly assigned to a 1: 1: 1 ratio in three groups including two intervention and one control groups.

Settings and conduct

After registry of trial, the researcher will identify eligible patients in Shahid Madani Cardiac Surgery ward, Tabriz. They will be included in the study if they are eligible and consented. The participants with GCS = 14-15 will receive intervention in cardiology Intensive Care Unit after surgery. Intervention will be performed in the first two days following surgery after extubation for both groups. The four-phase and three-phase protocol will be performed for the intervention groups. For the control group, routine intervention will be done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65, EF above 45%, no open sternectomy Exclusion criteria: Unstable angina, respiratory cardiac arrest during or after surgery, MV duration above 24 hours

Intervention groups

Intervention group 1: Quadruple protocol of moving in bed, sitting in bed next to bed, walking in ward and stepping on a pedestal, Intervention group 2: three-phase protocol including the necessary measures for lung clearance, walking in the ward and taking steps on a pedestal, and control group will receive routine intervention.

Main outcome variables

mean arterial oxygen saturation, Frequency of cognitive status and pulmonary complications, mean pain score, after intervention in study groups

General information

Reason for update

Identify information with the submitted article. The article is in the judging stage and one of the objections that must be resolved in order for the article to be accepted is the correction of the trial in the clinical trial center.

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025937N5**
Registration date: **2019-11-03, 1398/08/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-12, 1400/04/21**

Update count: **1**

Registration date

2019-11-03, 1398/08/12

Registrant information

Name

Aefeh Allahbakhshian

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2019-11-10, 1398/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The effect of early mobilization protocol at three and four phase on clinical outcome in patients undergoing coronary artery bypass graft:a single blinded randomized clinical trial

Public title

Comparison of The effect of early mobilization protocol at three and four phase on clinical outcome in patients undergoing coronary artery bypass graft:a single blinded randomized clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: 1. Selecting units from both ages 18 to 65 years 2. Having a BMI between 20 and 30 mg / m² 3. Stable hemodynamic status without taking inotropic drugs 4. Lack of arrhythmias and angina 5. No Significance of Respiratory Distress and RR under 20 without Symptoms of Systemic Infection. 6.Lack of Motor and Neurological Problems 7.Static pressure above 90 mmHg 8. Time of pump pulmonary than 90 minutes 9. As an expert in cardiac surgery 10. Having no previous history of pulmonary disease 11. A psychological and mental illness that will be examined by examining a patient's case and completing a mental-mental mental test questionnaire (MMSE) before entering the study. If the MMSE score of the patient in the heart surgery department and before entering the intensive care unit in the range of 30 -25 were enrolled in the study and will be excluded from the study if they have dementia and pathologic features.

Exclusion criteria:

Exclusion criteria: 1. Cardiovascular and respiratory tract during and after admission in the ICU 2. Time for mechanical ventilation over 24 hours 3. Heart rate above 120 or uncontrolled arrhythmias 4. Unstable angina 5. Open sternum 6. Oxygen substitution under 90 7. Taccharide and bradycardia 8. EF below 40 9. No ability to communicate after entering the intensive care unit 10. The chest tube thickness is more than 100 cc at four hours 11. The time of the heart-pulmonary pump is 90 minutes.

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Outcome assessor

- Data analyser

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

The present study is a single-blind randomized clinical trial with a three-arm parallel design. After obtaining the permission of the Ethics Committee and the registration of the study at the Iranian Center for Clinical Trials, available randomly selected samples will be randomly assigned with a 1: 1: 1 ratio in the control group and the first intervention group and the intervention group. Random assignment sequence by non-person involved in research using RAS software (Random Allocation Software) and random blocking will be generated using three and six blocks for assignment in three groups (two intervention groups and a control group). Became Hiding allocation based on the generated sequence will be done using matte envelopes, both closed and shaped, numbered from the number 1 to the end. The first person to enter the study will be enveloped No. 1, and this process will continue until the end . Therefore, the researcher and the person under study will not be informed of the type of allocation (Received Allocation Concealment) until the envelopes are unlocked. In this study, the statistical analyzes and the consequences of the outcome will only be blind. Information about the research objectives and its importance to the company They are given confidential information and their responses. Prior to the beginning of the study, written consent of each participant is taken.

Blinding (investigator's opinion)

Double blinded

Blinding description

Hiding allocation based on Sequence generated using opaque and envelope envelopes The shape numbered from the number 1 to the end will be done. The first person to be included in the study is envelope # 1 data And this process will continue until the end. So The researcher and the person under study were allotted Concealment) will not be known until the envelopes are opened Had In this analytical and statistical analytic study The consequences will only be blinding

Placebo

Not used

Assignment

Parallel

Other design features

Random allocation is done using computer random numbers table

Secondary Ids

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz University of Medical Sciences, Golgasht ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2019-09-11, 1398/06/20

Ethics committee reference number

lr.tbzmed.rec.1398.613

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**

Arterial oxygen saturation

Timepoint

Before the intervention, immediately after the intervention, 15 after intervention

Method of measurement

Using pulse oximetry and assessing arterial blood gases(ABG)

2**Description**

pain

Timepoint

Before the intervention, immediately after the intervention, 15 after intervention

Method of measurement

Analog visual analogue tool: VAS (Visual Analogue Scale)

3**Description**

Levels of cognitive status

Timepoint

Before the study, after reading and end intervention

Method of measurement

Short Psycho-Mental Testing Tool: MMSE (Mini-Mental State Examination)

4**Description**

Frequency of pulmonary complications

Timepoint

Before the intervention, on the last day of intervention

Method of measurement

Using CXR and Physician Visit

5**Description**

arterial blood gas

Timepoint

before intervention and after 15 minute after end intervention

Method of measurement

ABG

Secondary outcomes**1****Description**

Duration of stay in hospital and ICU

Timepoint

On the day of the patient's discharge from ICU and Hospital

Method of measurement

The patient's stay in the hospital and ICU will be determined by calculating the days of admission

Intervention groups**1****Description**

Intervention group 1: Implementation of four phase early movement protocol for Intervention group 1: Intervention will be performed in two days the first day 24 hours after surgery and after endotracheal tube removal and the second day 48 hours after surgery. The four-phase protocol of moving in bed, sitting in a chair next to the bed, walking in sections and stepping on a pedestal for the first group were compared and the results were compared using the scales listed in the tool section and compared with the other groups.

Category

Rehabilitation

2**Description**

Intervention group 2: Implementation of three-phase early motion protocol for intervention group 2: Intervention in two days, the first day 24 hours after surgery and after endotracheal tube removal and the second day 48 hours after surgery. The three-phase protocol will focus on the second intervention group, with more focus on pulmonary exercises (including the necessary steps to clear the lungs) (in the methodology section), walking the ward and taking steps on a pedestal. And the groups will be compared

Category

Rehabilitation

3**Description**

Control group: Perform routine procedures for the control group: The control group will receive routine actions that involve lowering the bed and walking in the ward 24 hours after surgery.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz University Of Medical Sciences

Full name of responsible person

Dr Atefeh Allahbakhshian

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Tabriz, Golghast St., Tabriz University of Medical Sciences

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

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Web page address**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 Atefeh Allahbakhshian

Position

PhD of nursing education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Tabriz School of Nursing and Midwifery, Southern Shariati St., Tabriz

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr Atefeh Allahbakhshian

Position

PhD of nursing education

Latest degree

Ph.D.

Other areas of specialty/work

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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

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

Requested data will be provided to researchers for statistical analysis of the submitted proposal (meta-analysis).

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 proposal to perform meta-analysis using IPD data after being unidentified. Also, in exceptional cases, data will be made available to journals for checking.

From where data/document is obtainable

Refer to the email address (allahbakhshiana@tbzmed.ac.ir).

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

The requests will be sent by email and data will be available within a week.

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Atefeh Allahbakhshian

Position

PhD of nursing education

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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