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

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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.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
- Outcome assessor
- Data analyser

Sample size
Target 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 committe 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
Ir.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 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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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
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Person responsible for updating data

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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
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