Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the Effect of Early Mobilization Program on Physiological Indicators and Cardiac Anxiety of Patients with Acute Myocardial Infarction

Protocol summary

Study aim
Determining the effect of patient's early mobility program on physiological parameters and heart-focused anxiety in patients with acute myocardial infarction

Design
Clinical trial with control group, with parallel groups, one-way blind,Randomized

Settings and conduct
Patients with acute myocardial infarction , hospitalized in the cardiac intensive care unit of 9 Dey and Shahid Ashrafi Khomeini Shahr hospitals, after obtaining written consent, are randomly divided into two groups of intervention and control. The statistical analyzer has only information about raw data

Participants/Inclusion and exclusion criteria
Inclusion criteria:Personal preference, age less than 75, hemodynamic stability, uncomplicated myocardial infarction, no history of previous myocardial infarction, no history of overdose use of beta-blockers, no contraindications to exercise and movement, no acute psychiatric disorders, Absence of complete heart block, atrial-ventricular block two and three, life-threatening dysrhythmia, inferior myocardial infarction, life-threatening cardiac complications and thrombophlebitis, no history of open heart surgery, discharge fraction more than 40,% Non-entry conditions: Inability of the patient to continue to participate in the study, inability to apply or follow the study protocol.

Intervention groups
Intervention group: Patients with acute myocardial infarction , during an early mobility program, after 6 hours of complete rest, step out of bed in 6 steps and monitor his vital signs. Before and after the intervention, the patient's cardiac anxiety questionnaire is completed. control group: Patients with acute myocardial infarction are admitted to the cardiac intensive care unit, who are discharged according to the ward routine

Main outcome variables
Blood pressure number, heart rate, arterial blood oxygen saturation, The cardiac anxiety questionnaire score

General information

Reason for update

Acronym
EM and MI Study

IRCT registration information
IRCT registration number: **IRCT20220116053740N1**
Registration date: **2022-05-01, 1401/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-01, 1401/02/11**
Update count: **0**

Registration date
2022-05-01, 1401/02/11

Registrant information

Name
Reihane Askari

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 3359 7811

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reyhaneaskari90@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effect of Early Mobilization Program on Physiological Indicators and Cardiac Anxiety of Patients with Acute Myocardial Infarction

Public title

Evaluation of the Effect of Early mobilization in Myocardial Infarction

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Personal Desire and Satisfaction of Patients to Participate in Research The Patient must be less than 75 Years old The Patient has Hemodynamic stability The Units to be studied are Uncomplicated Myocardial Infarction The Patient has no Previous history of Myocardial Infarction The Patient has no History of Overdosing on Beta-blockers No Sports Contraindications and Movement restrictions Absence of Acute psychiatric disorders Absence of Complete Heart Block, Atrioventricular Node two and three Block, Life-threatening Dysrhythmia, Inferior Myocardial Infarction, Life-Threatening Cardiac Complications and Thrombophlebitis Has not had any Open Heart Surgery Left Ventricular Ejection Fraction is more than 40%

Exclusion criteria:

The patient's unwillingness to continue participating in the study Inability to apply or follow the study protocol in terms of recurrence of previous physical and mental illness Physician diagnoses during the intervention that the subject units can not continue to participate in the study Occurrence of any threatening condition during the intervention in the patient that requires emergency nursing or medical intervention

Age

To **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the samples based on the inclusion criteria, the samples are placed in two groups of intervention and control using a table of random numbers. Thus, the researcher first determines that all patients to whom the even number is assigned are in the intervention group and patients to whom the odd number is assigned are in the control group. Then close the eyes and put your finger on one of the digits in the random table and write down the house number and the starting point number column. The direction of movement is set horizontally to the right, up and then to the left.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and statistical analyzers are blinded by protocol coding and questionnaires

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Hezar Jerib St. Isfahan University of Medical Sciences and Health Services, Building No. 4,

City

Isfahan

Province

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Postal code

8193933388

Approval date

2021-10-30, 1400/08/08

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.150

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction

ICD-10 code

I23.8

ICD-10 code description

Other current complications following acute myocardial infarction

Primary outcomes

1

Description

Physiological indicators

Timepoint
Before intervention, 24 hours after intervention, 72 hours after intervention
Method of measurement
Hemodynamic monitoring system, Checklist

Secondary outcomes

1

Description
Anxiety focused on the heart
Timepoint
Before and after the intervention
Method of measurement
The Cardiac Anxiety Questionnaire

Intervention groups

1

Description
Intervention group: Patients with acute myocardial infarction who begin to move as planned after 6 hours of complete rest.
Category
Other

2

Description
Control group: Patients with acute myocardial infarction, who begin to move according to the ward routine.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
9 Dey Manzariye Hospital
Full name of responsible person
Reihane Askari
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2

Recruitment center
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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
Esfahan 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

Esfahan University of Medical Sciences
Full name of responsible person
Reihane Askari
Position
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
Information about the original message and the study protocol and clinical report will be shared as an article
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
All people in the field of medicine and nursing
Under which criteria data/document could be used
People working on acute myocardial infarction
From where data/document is obtainable
Email to the person performing the project
What processes are involved for a request to access data/document
Email to the applicant, request from the Vice Chancellor for Research, if they agree, provide information to the applicant
Comments