Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of the start time of rehabilitation treatment on the functional outcome of patients with myocardial infarction under Primary PCI

Protocol summary

Study aim
Determining the effect of starting time of Cardiac rehabilitation treatment on diastolic failure rate, heart rate and quality of life

Design
A randomized clinical trial with a control group, without blinding, with parallel groups with 60 patients, envelope method will be use for randomization.

Settings and conduct
This study will be performed in Hamadan city in Besat Hospital on patients who are candidates for cardiac rehabilitation after primary PCI. In one group of patients cardiac rehabilitation will be performed after one month and in the other group after two months after primary PCI. The number of cardiac rehabilitation sessions will be 12 sessions over four weeks and the approximate duration of each rehabilitation session will be between 1 to 1.5 hours. Cardiac rehabilitation program includes: exercises activity : warm-up, aerobic exercises of the upper and lower limbs, and stretching exercises, and finally cooling respectively. The exact formulation of exercise and its intensity according to the patient's strength (Borg scale and Exercise stress test) will be done under the supervision of a physical therapist.

Participants/Inclusion and exclusion criteria
Patients with acute coronary syndrome, Inclusion criteria: Primary PCI, Have consent to participate in the study, Full consciousness. Exclusion criteria: premature death (less than 90 days after PCI), Systolic blood pressure above 180 and diastolic blood pressure above 110 mm Hg, uncontrolled malignant arrhythmia, major respiratory diseases and Inability to do exercise activity.

Intervention groups
In the first group, the onset of cardiac rehabilitation will be one month after PCI and in the second group, the onset of cardiac rehabilitation will be two months after PCI.

Main outcome variables
changes in the degree of diastolic failure and heart rate,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151123025202N18**
Registration date: **2021-12-27, 1400/10/06**
Registration timing: **prospective**

Last update: **2021-12-27, 1400/10/06**
Update count: **0**

Registration date
2021-12-27, 1400/10/06

Registrant information

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Abbas Moradi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of the start time of rehabilitation treatment on the functional outcome of patients with myocardial infarction under Primary PCI

Public title
Rehabilitation treatment of patients with myocardial infarction under Primary PCI
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Successful treatment of myocardial ischemia with PCI Be consciousness
Exclusion criteria:
Patients with cardiogenic shock Patients with premature death (less than 90 days after PCI) Uncontrolled malignant arrhythmia Major respiratory diseases Inability to do exercise program Systolic blood pressure above 180 mm Hg at rest Diastolic blood pressure above 110 mm Hg at rest
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
We made 60 cards and write letter I on 30 for Intervention and on the other 30 letter C for the control group. Then put them inside the envelope with aluminum wrap and put in a box. At the time of patient arrival, one of the envelopes randomly will be selected and will be opened, based on selected letter I or C patients will be assigned to intervention or control group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
No need to more information

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan Univercity of Medical Science
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838697
Approval date
2021-05-15, 1400/02/25
Ethics committee reference number
IR.UMSHA.REC.1400.157

Health conditions studied

1

Description of health condition studied
Acute myocardial ischemia
ICD-10 code
I24.9
ICD-10 code description
Acute ischemic heart disease, unspecified

Primary outcomes

1

Description
LVEF rate, diastolic failure degree
Timepoint
Before the start of rehabilitation and after the 12th rehabilitation session
Method of measurement
Eco cardiography

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before the start of rehabilitation and after the 12th rehabilitation session
Method of measurement
Using SF-36 Questionnaire

Intervention groups

1

Description
Intervention group: This group undergoes cardiac physiotherapy one month after primary PCI. The duration of cardiac rehabilitation is 12 continuous sessions in 4 weeks (3 sessions per week) and the duration of each session is 1 to 1.5 hours. Exercises programs for each session are warm up, aerobic exercises including walking on a treadmill or bicycle, strength training (both upper

and lower limbs with powerlifting) and stretching exercises, respectively (both upper and lower limbs) and cooling down will be done at the end. The exact formulation of exercise and its intensity is determined individually by the physical therapist according to the patient's abilityand his condition.

Category

Rehabilitation

2

Description

Intervention group: Physiotherapy in this group will be similar to the first group. With the difference that instead of one month, they will receive physiotherapy two months after primary PCI

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Lobat Majidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

dr Shokohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Abbas Moradi

Position

Coach

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Latest degree

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Person responsible for updating data

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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