

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Name

Abbas Moradi

Name of organization / entity

Hamedan University of Medical Of Science

Country

Iran (Islamic Republic of)

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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

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Shahid Fahmideh

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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 ability and 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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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

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

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