Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Study the outcomes of early hospital discharge in patients with ST Elevation Myocardial Infarction after primary PCI

Protocol summary

Study aim
Determining the Outcomes of Early Discharge of STEMI Patients after PCI Primary in Dr. Heshmat Hospital in Rasht in 1401-1402

Design
A clinical trial with control group, parallel groups, without blinding, randomized block, phase 3 performed on 228 patients. Random allocation is considered based on 114 4-fold blocks.

Settings and conduct
STEMI patients referred to Heshmat Hospital in Rasht will enter the study with inclusion criteria, which are subject to PCI primary.

Participants/Inclusion and exclusion criteria
Inclusion criteria: STEMI patients who undergo primary PCI with femoral access by an operator. Non-entry criteria: 1 _ They have life-threatening disease.2_ Left ventricular ejection fraction (LVEF) was less than 30%. 3_ Patient age over 75 years.4_Patient has pulmonary edema (Killip class II, III, IV) Exit Criteria: Patients who: 1_Each of the cases and criteria for occurrence of Major adverse cardiovascular events (MACE) including: acute myocardial infarction, acute coronary syndrome or ischemic heart disease (ACS/IHD), stroke (ischemic or hemorrhagic stroke), cardiovascular death (CV) and death by any cause.2_ Patients who were readmitted .3_ were not willing to continue participation in the research.4_Primary PCI with Axis-Radial were withdrawn from the design.

Intervention groups
The patients who met the inclusion criteria were divided into two groups with early discharge and no early discharge. The non-early discharge group was discharged from the hospital department after more than 72 hours according to the conventional protocol, and the group that underwent the intervention was discharged from the hospital within a period of 48 hours.

Main outcome variables
Total deaths, MI and stroke.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220809055645N5**
Registration date: **2023-05-26, 1402/03/05**
Registration timing: **prospective**

Last update: **2023-05-26, 1402/03/05**
Update count: **0**

Registration date
2023-05-26, 1402/03/05

Registrant information

Name
Fatemeh Baharvand

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3361 8177

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-05, 1402/03/15

Expected recruitment end date
2023-10-07, 1402/07/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study the outcomes of early hospital discharge in patients with ST Elevation Myocardial Infarction after primary PCI

Public title

Outcomes of early discharge in patients with myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

STEMI patients who undergo PCI primary with femoral access by an operator.

Exclusion criteria:

have had a life-threatening disease The left ventricular ejection fraction (LVEF) has been less than 30 percent. The patient's age is over 75 years old. The patient will have pulmonary edema (Killip class II,III,IV) Each of the cases and criteria for occurrence of Major adverse cardiovascular events (MACE) included: acute myocardial infarction, acute coronary syndrome or ischemic heart disease (ACS/IHD), stroke (ischemic or hemorrhagic stroke), cardiovascular death (CV), and death by any cause. Patients who were readmitted. were not willing to continue to participate in the research. Perform Primary PCI with Radial Access were removed from the design.

Age

To **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **228**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, in order to assign patients to intervention and non-intervention groups, a limited randomization approach with block randomization method will be used.Random allocation is considered based on 114 4-fold blocks. It is done through random allocation software.The sequence list of these patients is attached to the proposal. After the study, the list is kept in a sealed lock envelope at the Cardiac Research Center. After starting the study, this list is read daily and patients are placed in early discharge (A) and routine (B) groups according to the sequence of the list.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Guilan University of Medical Sciences

Street address

Namjoo

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2023-05-03, 1402/02/13

Ethics committee reference number

IR.GUMS.REC.1402.059

Health conditions studied

1

Description of health condition studied

ST elevation (STEMI) myocardial infarction

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

Total deaths

Timepoint

In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.

Method of measurement

Getting a report and follow up after discharge

2

Description

Myocardial Infarction

Timepoint

In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.

Method of measurement

Based on the ECG of the patient's blood pressure (relative to the basal state)

3

Description
Stroke
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
CT_SCAN MRI

Secondary outcomes

1

Description
Readmission
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Getting a report and follow up after discharge

2

Description
Require Revocularization
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Based on patient reference records, in-person examination in weeks 2 and 6

3

Description
Recurrent chest pain
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Getting a report and follow up after discharge

4

Description
Arrhythmias
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Based on the ECG of the patient's blood pressure (relative to the basal state)

5

Description
Acute recurrent myocardial infarction
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Based on the ECG of the patient's blood pressure (relative to the basal state)

6

Description
Acute recurrent Coronary Syndrome
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Based on the ECG of the patient's blood pressure (relative to the basal state)

7

Description
Compliance to the drug
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Getting a report after discharge and during secondary referral to follow up the patient's heart condition

8

Description
Lung edema
Timepoint
In the study, follow-up of patients during the 2nd and 6th weeks is performed in person by the attending physician to assess each of the mentioned outcomes.
Method of measurement
Use the Killip class criterion

Intervention groups

1

Description
Intervention group: They will be discharged from hospital within 48 hours.
Category
Treatment - Other

2

Description
Control group: According to conventional protocol, they will be discharged from the department after more than 72 hours.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmat Heart Hospital
Full name of responsible person
Fatemeh Baharvand
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Guilan University of Medical Sciences
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Parastar
City
Rasht
Province
Guilan
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41937-13111
Phone
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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
Rasht 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
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Position
Assistant Professor of Interventional Cardiology
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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
All data except personal information (name, contact number, file number) can be published.
When the data will become available and for how long
After publishing the results
To whom data/document is available
Available to service providers such as doctors and nurses.
Under which criteria data/document could be used
After obtaining permission from the project manager, the information will be usable.
From where data/document is obtainable
Project manager
What processes are involved for a request to access data/document
By email to the project manager
Comments
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