

# 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were readmitted .3\_ were not willing to continue participation in the research.4\_Primary PCI with Axis-Radial were withdrawn from the design.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)

##### Phone

+98 13 3361 8177

##### Email address

dr.baharcadio@gmail.com

##### 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 Revocalarization

#### **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  
**Street address**  
Kooye Bayani  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
41939-55588  
**Phone**  
+98 13 3366 4282  
**Email**  
dr.baharcadio@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Guilan University of Medical Sciences  
**Street address**  
Parastar  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
41937-13111  
**Phone**  
+98 13 3334 6489  
**Email**  
riasat@gums.ac.ir  
**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**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Baharvand  
**Position**  
Assistant Professor of Interventional Cardiology  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Cardiology  
**Street address**  
Kooye Bayani  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
41939-55588  
**Phone**  
+98 13 3366 4282  
**Email**  
dr.baharcadio@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Baharvand  
**Position**  
Assistant Professor of Interventional Cardiology  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Cardiology  
**Street address**  
Kooye Bayani  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
41939-55588  
**Phone**  
+98 13 3366 4282  
**Email**  
dr.baharcadio@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Baharvand  
**Position**  
Assistant Professor of Interventional Cardiology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Kooye Bayani

**City**

Rasht

**Province**

Guilan

**Postal code**

41939-55588

**Phone**

+98 13 3366 4282

**Email**

dr.baharcadio@gmail.com

**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**

-