

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of activation and implementation of the Code STEMI on "Door to balloon time" in patients with myocardial infarction with ST-segment elevation

#### Protocol summary

##### Study aim

Determine the effect of setting up the STEMI code on ;Door-to-balloon time; in Patients with ST stroke who referred to Boali Sina Hospital in Qazvin

##### Design

Semi-experimental study with control and intervention group, with available sampling, sample size equal to 50

##### Settings and conduct

This study will be carried out on patients who are referred to the hospital of Boali Sina Qazvin by EMS for signs of an acute myocardial infarction.

##### Participants/Inclusion and exclusion criteria

Entry requirements: All patients with acute and Typical heart disease referred by the EMS to a selected treatment center affiliated with Qazvin University of Medical Sciences and confirmed by the cardiologist to diagnose acute STEMI. Conditions of failure to enter: Referral of the patient to the hospital after more than 12 hours from the onset of pain. Referral of patient from other treatment centers. Patients hospitalized in other parts of the hospital who have had a new heart attack. Not satisfying the patient for primary angioplasty.

##### Intervention groups

The study has two groups of control and intervention. In the control group, the ; Door-to-balloon time; time, is measured and recorded without making any changes in the hospital's common practice in transferring these patients to the cath lab. In the intervention group, after entering these patients into the hospital, a team called "STEMI Code", consisting of an emergency medicine specialist, a cardiologist, two nurses and two crew, will be called up with specific job descriptions and the patient's condition will be required Perform angioplasty, and if confirmed, the patient is immediately transmitted to the Cath lab.; Door-to-balloon time; Time , is also measured and recorded for this group and finally compared with the control group.

#### Main outcome variables

Change in ; door to balloon time;

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20171210037814N1**

Registration date: **2018-03-13, 1396/12/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-13, 1396/12/22**

Update count: **0**

##### Registration date

2018-03-13, 1396/12/22

##### Registrant information

##### Name

Fateme Jalalian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3336 6428

##### Email address

f54.jalalian@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-03-20, 1396/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of activation and implementation of the Code STEMI on "Door to balloon time" in patients with myocardial infarction with ST-segment elevation

**Public title**

Effect of Code STEMI on "Door to balloon time"

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with acute and typical heart disease referred to the emergency department of the selected treatment center affiliated with Qazvin University of Medical Sciences. Patients should be referred by EMS. The diagnosis of acute STEMI in patients should be confirmed by a cardiologist.

**Exclusion criteria:**

Referral of the patient to the hospital after more than 12 hours from the onset of pain. Referral of patient from other treatment centers. Patients hospitalized in other parts of the hospital who have had a new heart attack. Not satisfying the patient for primary angioplasty.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

The study has two groups of patients with acute myocardial infarction, which, according to the time of referral to the hospital (before or after the start of the STEMI code), fall into one of the control or intervention groups.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Subcommittee on Biomedical Research in Qazvin University of Medical Sciences

**Street address**

Qazvin University of Medical Science and Health Services, Faculty of Nursing and Midwifery

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413768149

**Approval date**

2017-04-30, 1396/02/10

**Ethics committee reference number**

IR.QUMS.REC.1396.65

**Health conditions studied****1****Description of health condition studied**

Acute myocardial infarction

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

"Door to balloon" time

**Timepoint**

Before and after applying "STEMI code"

**Method of measurement**

Time recording

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: The control group is a patient who has been diagnosed with acute myocardial infarction with ST segment elevation before applying the "STEMI code", and transferring them to "cath lab", using the traditional hospital method.

**Category**

N/A

**2****Description**

Intervention group: The intervention group includes patients with acute myocardial infarction, which occurs

at a time when the STEMI code is launched. These patients are transmitted to the "Cath lab", by members of the STEMI code (with specific job descriptions).

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Boali sina hospital

**Full name of responsible person**

Jalalian Fateme

**Street address**

Naderi Blvd

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413768149

**Phone**

+98 28 3333 3031

**Email**

f54.jalalian@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Amir Peimani

**Street address**

Qazvin University of Medical Sciences, Qazvin, Iran

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413768149

**Phone**

+98 28 3336 6428

**Email**

f54.jalalian@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Qazvin 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**

Qazvin University of Medical Sciences

**Full name of responsible person**

Jalalian Fateme

**Position**

Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Qazvin University of Medical Sciences, Qazvin, Iran

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413768149

**Phone**

+98 28 3336 6428

**Email**

f54.jalalian@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr. Leili Yekefallah

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

Shahid Bahonar Blv, Qazvin

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413768149

**Phone**

+98 28 3336 6428

**Email**

leili\_fallah@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Jalalian Fateme

**Position**

Nursing student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Qazvin University of Medical Sciences, Qazvin, Iran

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413768149

**Phone**

+98 28 3336 6428

**Fax****Email**

f54.jalalian@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Given the multiple variables measured, and given that the data ultimately result in several articles, I do not plan

to publish it.

**Study Protocol**

No - There is not 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main results of the study are in the form of the article

**When the data will become available and for how long**

After completing the study and publishing the results as an article

**To whom data/document is available**

There is no limit to accessing for the results.

**Under which criteria data/document could be used**

To use its results for future studies.

**From where data/document is obtainable**

There is no limit to accessing for the results.

**What processes are involved for a request to access data/document**

Send an email to the owner of the project to receive the documentation.

**Comments**