

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Prevalence of non-sustained ventricular tachycardia in patients with STEMI with left ventricular ejection fraction (LVEF)<35 using holter monitoring at post-discharge intervals at Chamran hospital and its effect on major adverse cardiac events

#### Protocol summary

##### Study aim

1. Determining the frequency of NSVT in patients with myocardial infarction with cardiac output less than 35% at intervals of ten days within forty days after MI
2. Determination and comparison of MACE of patients with myocardial infarction in the group undergoing holter monitoring with the control group within three months after MI

##### Design

Diagnostic clinical trial with control group, not blinded, randomized, on 110 patients. Samples are randomly divided into two groups using random allocation software 2.0.

##### Settings and conduct

In this diagnostic randomized clinical trial, patients with myocardial infarction with LVEF <35% treated with PCI in Isfahan Chamran Hospital for ventricular arrhythmia during 40 days after MI to evaluate Frequencies are studied.

##### Participants/Inclusion and exclusion criteria

Over 18 years old, Consent to enter the study, Myocardial infarction (ST-segment elevation of one millimeter or more in at least two adjacent leads) with heart failure (LVEF <35%)

##### Intervention groups

Intervention group (n = 55): Patients with myocardial infarction with cardiac output less than 35% who underwent PCI, undergo Holter monitoring every ten days for the first 40 days after discharge. After discharge, at ten-day intervals, using a 24-hour Holter monitoring, they are examined for the presence of NSVT, and if NSVT is diagnosed and if VT is induced, ICD will be placed. In the control group, every ten days during the first 40 days after discharge and then three months later, through a telephone call, the class function, stroke, MI will be asked again, and in case of hospitalization or

death in the hospital, the cause will be investigated. File and in case of sudden death at home, information will be obtained and recorded.

##### Main outcome variables

1. Incidence of NSVT
2. MACE (major cardiac complications including stroke, myocardial infarction and cardiovascular death) patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210625051701N1**

Registration date: **2021-07-24, 1400/05/02**

Registration timing: **prospective**

Last update: **2021-07-24, 1400/05/02**

Update count: **0**

##### Registration date

2021-07-24, 1400/05/02

##### Registrant information

##### Name

Mohamad mahdi Mahmoudi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2246 5035

##### Email address

mm.mahmoudi70@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2021-08-11, 1400/05/20

**Expected recruitment end date**

2022-03-20, 1400/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Prevalence of non-sustained ventricular tachycardia in patients with STEMI with left ventricular ejection fraction (LVEF)<35 using holter monitoring at post-discharge intervals at Chamran hospital and its effect on major adverse cardiac events

**Public title**

Prevalence of unstable ventricular tachycardia using Holter monitoring in patients with myocardial infarction with cardiac output less than 35%

**Purpose**

Diagnostic

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

Over 18 years old Consent to enter the study Myocardial infarction (ST-segment elevation of one millimeter or more in at least two adjacent leads) with heart failure (LVEF <35%)

**Exclusion criteria:**

Dissatisfaction with the study Previous history of myocardial infarction Having life-threatening diseases before having a myocardial infarction Patients with left bundle branch block on electrocardiogram Patients with dangerous cardiac conditions who are bedridden Previous history of arrhythmia Previous history of chronic heart failure Monomorphic arrhythmia in the first 24 hours Patients who have undergone CABG Previous history of chronic renal failure

**Age**From **18 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **110****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method is such that the samples are randomly divided into two groups with the help of random allocation software 2.0 designed by Dr. Mahmoud Saghaei. Patients are assigned to one of the two groups in order of enrollment by number. This is done by a nurse outside the research team and the groups are marked with the letters A and B.

**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**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, School of Medicine

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2021-01-11, 1399/10/22

**Ethics committee reference number**

IR.MUI.MED.REC.1399.907

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

ST elevation myocardial infarction (STEMI)

**ICD-10 code**

I21

**ICD-10 code description**

ST elevation myocardial infarction (STEMI)

**Primary outcomes****1****Description**

Prevalence of NSVT

**Timepoint**

Every ten days for the first 40 days after discharge

**Method of measurement**

Holter monitoring

**2****Description**

Incidence of MACE (major cardiac complications including stroke, myocardial infarction and cardiovascular death) in patients

**Timepoint**

Every ten days for the first 40 days after discharge  
**Method of measurement**  
Holter monitoring

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Intervention group: Patients with myocardial infarction with cardiac output less than 35% undergoing PCI . In the intervention group, forty days after admission, patients underwent cardiac rhythm monitoring four times in ten days intervals with a 24-hours Holter monitoring device, and the results were recorded. Each time the patient's rhythm changes will be interpreted by an electrophysiologist and the patient's arrhythmias will be recorded in a questionnaire. If there is intermittent ventricular tachycardia (less than 30 seconds) in the Holter monitoring, patients will be electrophysiologically studied by an electrophysiologist and in the case of ventricular tachycardia, ICD will be implanted. Finally, after three months, patients are contacted and asked about major cardiovascular complications (stroke, re-stroke, cardiovascular death) and information will be documented.

#### Category

Diagnosis

### 2

#### Description

Control group: In the control group, Holter monitoring and electrophysiological study will not be performed. Finally, after three months, patients are contacted and asked about major cardiovascular complications (stroke, re-stroke, cardiovascular death) and information will be documented and will be compared to the intervention group by statistical analysis.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Chamran Heart Educational, Medical and Research Center

##### Full name of responsible person

Afshin Amirpour

##### Street address

Bozorgmehr Bridge - Third Mushtaq St. - Chamran Hospital

##### City

Isfahan

##### Province

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##### Phone

+98 31 3260 0961

##### Email

Afshinamirpour.ras@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Amirhossein Azhari

##### Street address

Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, School of Medicine

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info@drazhari.ep.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Afshin Amirpour

##### Position

Fellowship in Angiography

##### Latest degree

Specialist

##### Other areas of specialty/work

Cardiology

**Street address**

Bozorgmehr Square, third Mushtaq Street, after the Shahrestan bridge. Shahid Chamran Clinic

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Afshin Amirpour

**Position**

Fellowship in Angiography

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra Mohammadi

**Position**

Cardiology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

**Street address**

Esfahan. Bozorgmehr. North Hamzeh Street. Alley 31. No. 134. Unit 3

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**Email**

Nazila\_2md@yahoo.com

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

Yes - There is 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

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

The study results will be published as an article. The study protocol and statistical analysis used in the article will be considered.

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

It will be published a year after the study is completed and will be available in the sources.

**To whom data/document is available**

Information will be made available after permission of the sponsor for academic researchers, physicians, and academic institutions .

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

Other researchers can use the results of the study in their review and meta-analysis.

**From where data/document is obtainable**

Dr. Afshin Amirpour Angiography subspecialty fellowship Isfahan: Bozorgmehr Square, third Mushtaq Street, after the Shahrestan bridge. Shahid Chamran Clinic Afshinamirpour.ras@gmail.com 0913 107 2678

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

upon request, the corresponding author will respond after consulting with the sponsor of the study.

**Comments**