Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 manturing 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
Isfehan
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

Isfehan

Postal code

۸۱۵۸۳۸۸۹۹۴

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

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

info@drazhariep.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
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 913 107 2678
Email
Afshinamirpour.ras@gmail.com

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
Street address
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Province
Isfehan
Postal code
8174673461
Phone
+98 913 107 2678
Email
Afshinamirpour.ras@gmail.com

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
City
Isfahan
Province
Isfehan
Postal code
8158658591
Phone
+98 919 217 0441
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 Ṣhahrestan 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