

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of timing of Heparin injection on the TIMI Flow grade in the STEMI patients undergoing primary PCI

Protocol summary

Primary outcome : assessment of TIMI Flow grade

Study aim

The effect of timing of Heparin injection on the Thrombolysis in Myocardial Infarction (TIMI) Flow grade in the ST Elevation Myocardial Infarction (STEMI) patients undergoing primary Percutaneous Coronary Intervention (PCI)

Design

This study is a Clinical trial with parallel groups, Phase 3, on 120 randomized patients. Subject are randomly assigned into two groups using the random block method with size 4. Random sequences will be generated using computer. After generating the list, a specific code will be assigned to each person. Registration and the sequence of random allocation is done by a third person. The sampling method is consecutive. Sampling is started based on the patients' gradual referrals to the emergency and completed documents, and will be continued to reach the required sample size.

Settings and conduct

This study will be done in the Heshmat hospital of university of Guilan. Clinical data about myocardial infarction, coronary angiography and angioplasty will be gathered from completed medical documents. Clinical data about Left Ventricular Ejection Fraction (LVEF) and improvement in LVEF will be assessed after 40 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ST Elevation Myocardial Infarction (STEMI) who are willing to participate in this study. The exclusion criteria : patients receiving thrombotic medicine during past seven days, pregnancy, active bleeding, thrombocytopenia history with heparin (HIT) , receiving heparin before hospitalization , thrombocytopenic patients, history of CABG, Age over 75 and failed PCI

Intervention groups

Intervention group (bolus 90 u/kg IV heparin UFH in emergency) and Control group (bolus 90 u/kg IV heparin as hospital routine and during PCI).

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200510047380N1**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Aboozar Fakhri Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3366 4282

Email address

aboozar.mousavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of timing of Heparin injection on the TIMI Flow grade in the STEMI patients undergoing primary PCI

Public title

Effect of timing of heparin injection on acute STEMI treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with STEMI who are willing to participate in this study

Exclusion criteria:

Patients receiving thrombotic medicine during past seven days
Pregnancy
Active bleeding
Thrombocytopenia history with heparin
Receiving heparin before hospitalization
History of thrombocytopenia
History of CABG
Age over 75
Failed Primary PCI

Age

To 75 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects with eligible criteria are randomly assigned into two groups using the random block method with size 4. These patients will be divided into two groups: early heparin administration group in the emergency department, and late heparin administration group in the cath lab unit. Random sequences will be generated using computer. After generating the list, a specific code will be assigned to each person, and will be identified by it during the study. Registration and the sequence of random allocation is done by a third person. The sampling method is consecutive. Sampling is started based on the patients' gradual referrals to the emergency department and completed documents, and will be continued to reach the required sample size.

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 Guilan University of Medical Sciences

Street address

Vice-Chancellor For Research and Technology of Guilan University of Medical Sciences, in front of 17 Shahrvivar hospital, Shahid Siadati street, Namjoo street, Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.GUMS.REC.1399.059

Health conditions studied

1

Description of health condition studied

Acute myocardial infarction with ST elevation

ICD-10 code

I21.0

ICD-10 code description

ST elevation (STEMI) myocardial infarction of anterior wall

Primary outcomes

1

Description

TIMI Flow grade

Timepoint

Once during coronary Angiography and before angioplasty, then after Primary PCI over culprit vessel

Method of measurement

Coronary Angiography

Secondary outcomes

1

Description

Left Ventricular Ejection Fraction (LVEF)

Timepoint

40 days after STEMI

Method of measurement

Echocardiography

2

Description

Pericardial effusion

Timepoint

40 days after STEMI

Method of measurement

Echocardiography

3

Description

Free wall rupture

Timepoint

40 days after STEMI

Method of measurement

Echocardiography

4

Description

FLAIL Mitral valve

Timepoint

40 days after STEMI

Method of measurement

Echocardiography

5

Description

Ventricular Septal Rupture (VSR)

Timepoint

40 days after STEMI

Method of measurement

Echocardiography

Intervention groups

1

Description

Intervention group: Patients with STEMI in intervention group whom will receive bolus dose of 90u/kg IV heparin UFH in emergency department

Category

Treatment - Drugs

2

Description

Control group: bolus 90 u/kg IV heparin as hospital routine and during PCI.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat heart hospital

Full name of responsible person

Seyed Aboozar Fakhr Mousavi

Street address

Heshmat Heart Hospital, Mosalla square, Rasht

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fakhrmousavi@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor For Research and Technology of Guilan University of Medical Sciences

Full name of responsible person

Mohammadreza Naghipour

Street address

Vice-Chancellor For Research and Technology, In front of 17 Shahrivar hospital, Shahid Siadati Street, Namjoo Street, Rasht

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research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor For Research and Technology of Guilan 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

Healthy Heart Research Center of Guilan University of
Medical Sciences

Full name of responsible person

Seyed Aboozar Fakhr Mousavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Healthy Heart Research Center, Heshmat Heart
Hospital, Mosalla square, Rasht

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Person responsible for updating data

Contact

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Full name of responsible person

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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

Undecided - It is not yet known if there will be 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

Spss file will include all data about acute MI (onset of chest pain, duration of chest pain, anterior, lateral, high lateral, extensive anterolateral, inferior, posterior, septal, RV MI), LVEF during hospitalization, heart rate on the electrocardiogram, systolic and diastolic blood pressure, killip class, treatment group, Early Bolus heparin administration in emergency department and Late bolus heparin in the catch lab, and referring for CABG. Angiographic and angioplasty data including Identifiable culprit vessel, vascular access TIMI FLOW of culprit vessel: LM, LAD, Diagonal, LCX, OM, RCA, PDA Before and after Primary PCI, HOSPITAL complications (stent thrombosis, local side effects of angiography including bleeding and hematoma, ventricular tachyarrhythmia (VT, VF) Flail MV, Vntricular septal rupture, free wall rupture, pericardial effusion. Clinical data about LVEF 40 days after STEMI.

When the data will become available and for how long

6 month after the results are published, the access period will be start.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

To obtain new results, researchers will be permitted to use further analysis and the data in the future researches.

From where data/document is obtainable

Healthy Heart Research Center, Dr Heshmat heart hospital, Mosalla Square, Rasht, Guilan, Iran Phone number: 00981333664282 P.O.Box: 41939-55588 Fax: 00981333668718

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

A written request with sufficient detail should be sent to the postal address. After receiving the request, the scientific correspondence author will be responsive within one week.

Comments