Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

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

Primary outcome : assessment of TIMI Flow grade

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 Fakhr 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, infront of 17 Shahrivar 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
City
Rasht
Province
Guilan
Postal code
41939-55588
Phone
+98 13 3366 4282
Email
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
City
Rasht
Province
Guilan
Postal code
41446-66949
Phone
+98 13 3333 5821
Email
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

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

City
Rasht

Province
Guilan

Postal code
41939-55588

Phone
+98 13 3366 4282

Email
fakhrmousavi@gums.ac.ir

Person responsible for scientific 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

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

City
Rasht

Province
Guilan

Postal code
41939-55588

Phone
+98 13 3366 4282

Email
fakhrmousavi@gums.ac.ir

Person responsible for updating data

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

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

City
Rasht

Province
Guilan

Postal code
41939-55588

Phone
+98 13 3366 4282

Email
fakhrmousavi@gums.ac.ir

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 angioplastic 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