

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Rivaroxaban Versus Warfarin in Patients With Left Ventricular Thrombus After Acute Myocardial Infarction: A Randomized Controlled Pilot Trial

Protocol summary

Study aim

Comparison of the safety of rivaroxaban-based versus warfarin-based antithrombotic regimens in patients with acute ST elevation myocardial infarction left ventricular thrombosis

Design

Two parallel groups randomized trial with blinded outcome assessment

Settings and conduct

The trial will take place in hospital setting (Rajaie cardiovascular medical and research center along with Tehran heart center) on patients with acute STEMI complicated by LVT. Patients will be randomized via central web based method into two interventional groups with two different antithrombotic regimen. Treating physician and patients will not be blinded. Thrombus status (assessed via echocardiography) and bleeding complications will be evaluated after 1 and 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. All patients with the age of 18-80 admitted with an acute STEMI 2. Presence of left ventricular thrombosis, confirmed by transthoracic echocardiography 3. Signed informed consent Exclusion criteria: 1. Previous history of mechanical prosthetic heart valve 2. Candidate for coronary artery bypass graft surgery 3. Active bleeding 4. Cardiogenic shock 5. Acute kidney injury or chronic kidney disease with a GFR<30 ml/min 6. Liver failure(Child-Pugh class C) 7. Sensitivity or intolerance with rivaroxaban/warfarin

Intervention groups

The study contains two groups: - Intervention: rivaroxaban (15 mg daily, oral) plus clopidogrel (75 mg daily, oral) plus ASA (80 mg daily, oral; only during the first 7 days) - Control: warfarin (target INR of 2.0-3.0) plus clopidogrel(75 mg daily, oral) plus ASA (80 mg daily, oral; only during the first 7 days)

Main outcome variables

LVT resolution; LVT size; thromboembolic events; all-cause death; bleeding

General information

Reason for update

There were few cases limited to acute STEMI who have undergone PCI. Consequently we have expanded our inclusion criteria to all patients complicating with acute STEMI

Acronym

IRCT registration information

IRCT registration number: **IRCT20181022041406N4**
Registration date: **2020-07-30, 1399/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **1**

Registration date

2020-07-30, 1399/05/09

Registrant information

Name

Parham Sadeghipour

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2092

Email address

psadeghipour@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Rivaroxaban Versus Warfarin in Patients With Left Ventricular Thrombus After Acute Myocardial Infarction: A Randomized Controlled Pilot Trial

Public title
Rivaroxaban in Left Ventricular Thrombus

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with the age of 18-80 admitted with an acute STEMI Presence of LV thrombosis, which were confirmed by transthoracic echocardiography Signed informed consent

Exclusion criteria:
Previous history of mechanical prosthetic heart valve
Candidate for coronary artery bypass graft surgery
Active bleeding Cardiogenic shock Acute Kidney Injury or Chronic Kidney Disease with a glomerular filtration rate <30 ml/min Liver failure (Child-Pugh class C) Sensitivity or intolerance to rivaroxaban/warfarin/P2Y12 inhibitors

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed via permuted block randomization method. Allocation will be generated via a web based system and consequently concealment will be central using computer software. Unit of randomization will be individual patients and no stratification will be applied.

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding will be performed only for the adjudicator level and analyzer level, and patients and physicians won't be blind in this study

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Heart Center

Street address

Tehran Heart Center, Jalal-e-Al-e-Ahmad Hwy, Northern Kargar Ave, Tehran province, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1416753955

Approval date

2020-06-08, 1399/03/19

Ethics committee reference number

IR.TUMS.THC.REC.1399.004

Health conditions studied

1

Description of health condition studied

Pre-acute ST-segment Elevation Myocardial Infarction (STEMI) Left Ventricular (LV) thrombosis

ICD-10 code

I23.6

ICD-10 code description

Thrombosis of atrium, auricular appendage, and ventricle as current complications following acute myocardial infarction

Primary outcomes

1

Description

Resolution of left ventricular thrombus

Timepoint

3 months after initiation of antithrombotic therapeutic regimen

Method of measurement

Transthoracic echocardiography

Secondary outcomes

1

Description

Bleeding after initiation of antithrombotic regimen

Timepoint

1 month and 3 months after initiation of antithrombotic regimen

Method of measurement

ISTH criteria

Intervention groups

1

Description

Intervention group: Rivaroxaban-based antithrombotic therapeutic regimen

Category

Treatment - Drugs

2

Description

Control group: Warfarin-based antithrombotic therapeutic regimen

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie cardiovascular medical and research center

Full name of responsible person

Parham Sadeghipour

Street address

Vali-Asr ave, Hashemi Rafsanjani Exp

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie cardiovascular medical and research center

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fnoohi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rajaie cardiovascular medical and research center

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

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Parham Sadeghipour

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

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Name of organization / entity

Rajaie cardiovascular medical and research center

Full name of responsible person

Parham Sadeghipour

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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