Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of rivaroxaban treatment in comparison with warfarin on the resolution, size, mobility and morphology of left ventricular apical thrombus and also comparing the incidence of bleeding, readmission, embolic events and cardiovascular events in patients with acute coronary syndrome

Protocol summary

Study aim
Evaluation of the effect of rivaroxaban treatment in comparison with warfarin in patients with acute coronary syndrome

Design
Clinical trial with control group with parallel groups, phase 2-3 on 60 patients

Settings and conduct
This study is performed in Chamran Hospital in Isfahan. Patients will be treated with anticoagulants in two ways. The first group receives rivaroxaban tablets and the second group receives warfarin tablets. This study is not blind. After treatment, the characteristics of thrombosis and cardiovascular events in patients will be evaluated and compared 3 months after treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age over 18 years, acute coronary syndrome, treated with aspirin and Plavix Exclusion criteria: renal and hepatic insufficiency, contraindications to anticoagulant therapy, major trauma, uncontrolled hypertension

Intervention groups
Intervention group 1: In this group, patients undergo echocardiography and after the initial anticoagulant treatment, rivaroxaban 15 mg tablets will be used every 12 hours for 21 days and then 20 mg daily. Resolution, size, mobility and morphology of left ventricular apical thrombus as well as comparison of bleeding, readmission, embolic events and major cardiovascular events in patients 3 months after treatment will be evaluated. Intervention group 2: In this group, patients undergo echocardiography and after the initial anticoagulant treatment, warfarin tablets will be used daily to maintain the INR between 2 and 3. Resolution, size, mobility and morphology of left ventricular apical thrombus as well as comparison of bleeding, readmission, embolic events and major cardiovascular events in patients 3 months after treatment will be evaluated.

Main outcome variables
Resolution, size, mobility and morphology of left ventricular apical thrombus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210614051574N9**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information

Name
Ghasem Mohammadsharifi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3729 4005

Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-03, 1400/12/12
Expected recruitment end date
2022-05-02, 1401/02/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of rivaroxaban treatment in comparison with warfarin on the resolution, size, mobility and morphology of left ventricular apical thrombus and also comparing the incidence of bleeding, readmission, embolic events and cardiovascular events in patients with acute coronary syndrome

Public title
Treatment with rivaroxaban compared with warfarin in patients with acute coronary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Acute coronary syndrome Treated with aspirin and Plavix
Exclusion criteria:
Renal and hepatic failure Existence of contraindications to anticoagulant therapy Major trauma Uncontrolled hypertension
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Esfahan University of Medical Sciences
Street address
Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-11-10, 1399/08/20
Ethics committee reference number
IR.MUI.MED.REC.1399.710

Health conditions studied

1

Description of health condition studied
Acute coronary syndrome
ICD-10 code
I24
ICD-10 code description
Other acute ischemic heart diseases

Primary outcomes

1

Description
Left ventricular morphology information
Timepoint
3 months after starting the study
Method of measurement
Eco cardiography

2

Description
Bleeding
Timepoint
3 months after starting the study
Method of measurement
Review the case and follow up with the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, patients undergo echocardiography and after the initial anticoagulant treatment, rivaroxaban 15 mg tablets from Abureyhan Company will be used every 12 hours for 21 days and then 20 mg daily. Resolution, size, mobility and morphology of left ventricular apical thrombus by echocardiography as well as comparison of bleeding, readmission, embolic events and major cardiovascular events in patients 3 months after treatment will be evaluated.

Category

Treatment - Drugs

2

Description

Intervention group 2: In this group, patients undergo echocardiography and after the initial anticoagulant treatment, 5 mg warfarin tablets from Abureyhan Company will be used daily to maintain the INR between 2 and 3. Resolution, size, mobility and morphology of left ventricular apical thrombus by echocardiography as well as comparison of bleeding, readmission, embolic events and major cardiovascular events in patients 3 months after treatment will be evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Chamran hospital
Full name of responsible person
Mohmmad Hadi Mansouri
Street address
No. 22, Roshd Ave., Daneshgah Blvd., Isfahan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan
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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
Mohammad Hadi Mansouri
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for scientific inquiries

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Full name of responsible person

Mohammad Hadi Mansouri

Position
Assistant professor

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Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is 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
All data can be shared after people have requested.

When the data will become available and for how long
Six months after publishing the results.

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable
Website of the Research Committee of Isfahan University of Medical Sciences

What processes are involved for a request to access data/document
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments