Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Effectiveness and safety of Apixaban versus Warfarin in patients with left ventricular thrombus following acute myocardial infarction: A randomized clinical trial

Protocol summary

Study aim
Reducing the risk of bleeding in patients and providing newer and more effective solutions to doctors in managing different spectrums of myocardial infarction patients

Design
Clinical trial with a control group, with parallel group, double-blind, randomized, phase 2-3 on 104 patients. The stratified block randomization method will be used for randomization.

Settings and conduct
This study will be conducted in Dr. Heshmat Hospital in Rasht. This study will be double-blinded, in which participants and outcome assessors will be blinded.

Participants/Inclusion and exclusion criteria
Inclusion: All patients with left ventricular thrombosis within two weeks after acute myocardial infarction, if they do not have contraindications to the use of anticoagulants. Exclusion: History of active bleeding, History of coagulation disorders, Contraindications to Apixaban or warfarin (For example, in patients with ESRD), Drug sensitivity to Apixaban or warfarin, Moderate to severe mitral stenosis, Mechanical valve disease, GFR less than 25, If INR is not within the control-normal range, i.e. 2 to 3, Consumption of drugs which interfere with Apixaban (such as amiodarone, antifungal drugs, anti-AIDS drugs, etc.)

Intervention groups
Including 52 patients with left ventricular thrombosis caused by myocardial infarction, for whom apixaban will be prescribed. In this way, the patients of this group will take 5 mg of apixaban twice a day. If the patient has two of the three conditions: weight less than 60 kg, age more than 80 years, and creatinine above 1.5, instead of 5 mg apixaban, he will receive a dose of 2.5 mg.

Main outcome variables
Reduction of thrombosis and bleeding in patients with left ventricular thrombosis following acute myocardial infarction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220809055645N1**
Registration date: **2022-08-13, 1401/05/22**
Registration timing: **prospective**

Last update: **2022-08-13, 1401/05/22**
Update count: **0**

Registration date
2022-08-13, 1401/05/22

Registrant information

Name
Fatemeh Baharvand

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness and safety of Apixaban versus Warfarin in patients with left ventricular thrombus following acute myocardial infarction: A randomized clinical trial

Public title

Comparing the efficacy and safety of apixaban compared to warfarin in patients with left ventricular thrombosis after acute myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with left ventricular thrombosis within two weeks after acute myocardial infarction, if there is no contraindication to the use of anticoagulants

Exclusion criteria:

History of active bleeding, History of coagulation disorders, Contraindications to Apixaban or warfarin (For example, in patients with ESRD), Drug sensitivity to Apixaban or warfarin, Moderate to severe mitral stenosis, Mechanical valve disease, GFR less than 25, If INR is not within the control-normal range, i.e. 2 to 3, Consumption of drugs which interfere with Apixaban (such as amiodarone, antifungal drugs, anti-AIDS drugs, etc.)

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of sampling and randomization of this clinical trial study will be stratified blocked randomization. In this way, each person was randomly assigned to the intervention or control group using 4 random blocks in a ratio of 1:1. In this method, one of the letters A or B will be assigned to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the purpose of blinding in this study, the desired drugs, i.e. Apixaban and Warfarin, will be purchased with the budget of the project. Then they will be transferred to identical cans in terms of shape and color. There will be no name or sign of the drugs on the cans. And they will be coded only with A and B. To preserve the properties of medicines, we will put them in dark cans (not glass) and away from light. The doctor who prescribes anticoagulant drugs will be the drug allocator in this plan, who will randomly assign cans A or B to patients. It should be noted that the prescribing physician is not blinded in this study. None of the patients in the plan will know what anticoagulant they are being treated with, and as a result, the study subjects will be blinded. In addition, the physician evaluating the results, who is the one who examines the size change and disappearance of left ventricular thrombus, in this study does not know which patient has received which drug and which group he is in. The same doctor will also check the patient's tests. Therefore, the echocardiography fellowship partner of the project in this study will evaluate the consequences of the use of prescribed anticoagulants by performing echocardiography, and he also does not know what kind of medicine the patient was treated with. Therefore, the co-evaluator of this study will also be blind. As a result, this study will be conducted in a double-blind manner.

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

Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square, Guilan, Rasht, Iran

City

Rasht

Province

Guilan

Postal code

4193955588

Approval date

2022-07-13, 1401/04/22

Ethics committee reference number

IR.GUMS.REC.1401.229

Health conditions studied

1

Description of health condition studied

Left ventricular thrombosis following acute myocardial infarction

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
Reduction of thrombosis and bleeding in patients with left ventricular thrombosis after acute myocardial infarction
Timepoint
At the beginning of the study, 3 months after the intervention
Method of measurement
By Echocardiography

Secondary outcomes

1

Description
Elimination of thrombus or change in size and its organization in the three-month follow-up, reduction of stroke and other thromboembolic events.
Timepoint
Three months after the intervention
Method of measurement
By Echocardiography

Intervention groups

1

Description
Intervention group: Including 52 patients with left ventricular thrombosis after myocardial infarction who will enter the study with personal consent and after completing the informed consent form. Apixaban anticoagulant will be prescribed for the participants in the intervention group. In this way, the patients of this group will take apixaban 5 mg twice a day, from the time the left ventricular thrombosis is seen until the end of the study, that is, up to three months after the start of the intervention. If the patient has two of the three conditions: weight less than 60 kg, age more than 80 years, and creatinine above 1.5, instead of 5 mg apixaban, he will receive a dose of 2.5 mg.
Category
Treatment - Drugs

2

Description
Control group: It will include 52 patients with left ventricular thrombosis caused by myocardial infarction, who will enter the study with personal consent and after completing the informed consent form. Warfarin will be prescribed for the participants in the control group. In this way, the patients of the control group will be asked to take warfarin 5 mg once a day. In the control group (warfarin user group), patients are treated with combined low molecular weight heparin (LMWH) and warfarin for at least 5 days as soon as left ventricular thrombosis is diagnosed. Whenever the patient's INR is in the therapeutic range (2-3) for at least 3 days, LMWH will be stopped and warfarin alone will be continued. It should be noted that warfarin dose adjustment in the group receiving warfarin is based on the INR level of the patients and this INR should be maintained throughout the study. Therefore, at any stage of the study, if the patient's INR is outside the normal range of 2 to 3, the patient will be excluded from the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Heshmat heart hospital
Full name of responsible person
Fatemeh Baharvand
Street address
Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square, Guilan, Rasht, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
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Cardiovascular Diseases Research Center, Dr. Heshmat Heart Hospital, 15th of Khordad Street, Mosalla Square, Guilan, Rasht, Iran
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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Fatemeh Baharvand

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Baharvand

Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patients' information will be kept confidential and it will be only available to this project's researchers.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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
No - There is not a plan to make this available

Data Dictionary
Not applicable