

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effectiveness of with different types of anticoagulants treatment in patients with atrial fibrillation in one-year follow-up in preventing stroke and bleeding complications comparison of drugs warfarin rivaroxaban and apixaban

Protocol summary

Study aim

Evaluation of the effectiveness of with different types of anticoagulants treatment in patients with atrial fibrillation in one-year follow-up in preventing stroke and bleeding complications Identifying the best treatment option among available anticoagulants to prevent stroke and bleeding events in patients with atrial fibrillation

Design

Clinical trial, parallel group trial with blinded, randomised outcome assessment, a phase 2 trial on 198 patients

Settings and conduct

The aim of the present study was to evaluate the effectiveness of one-year anticoagulants (rivaroxaban, apixaban and warfarin) for preventing stroke and bleeding complications in atrial fibrillation patients referred to Imam Khomeini Hospital in Ahvaz. Therapeutic effectiveness is measured by clinical examinations, coagulation tests, haemoglobin nad platelet count. This double blind clinical trial is based on the protocol in in which neither the participants nor the data analyzer knows which treatment or intervention participants are receiving until the clinical trial is over.

Participants/Inclusion and exclusion criteria

Exclusion criteria: 1-Patients treated with multiple oral anticoagulants 2-Taking multiple doses of the drug 3-Taking drugs with indications other than prevention of stroke and hemorrhage 4-Loss to follow-up before 1 year 5-Patients without comorbidity known to be associated with higher mortality, such as heart failure, cancer, chronic pulmonary disease Inclusion criteria: 1-Age > 18 years 2-Diagnosis of atrial fibrillation 3-Informed consent to participate in the study 4-Elevated CHA2DS2-VASc score of 2 or greater in men or 3 or greater in women

Intervention groups

1- Rivaroxaban recipients 2- Apixaban recipients 3- Warfarin recipients

Main outcome variables

Minor and major bleeding; Ischemic stroke; Systemic embolism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220404054402N1**

Registration date: **2022-06-10, 1401/03/20**

Registration timing: **prospective**

Last update: **2022-06-10, 1401/03/20**

Update count: **0**

Registration date

2022-06-10, 1401/03/20

Registrant information

Name

zahra khademi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 8037

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zahrakhademi157@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2022-09-09, 1401/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of with different types of anticoagulants treatment in patients with atrial fibrillation in one-year follow-up in preventing stroke and bleeding complications comparison of drugs warfarin rivaroxaban and apixaban

Public title

Evaluation of the effectiveness of with different types of anticoagulants treatment in patients with atrial fibrillation in one-year follow-up in preventing stroke and bleeding complications

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age > 18 years Diagnosis of atrial fibrillation Informed consent to participate in the study Elevated CHA2DS2-VASc score of 2 or greater in men or 3 or greater in women

Exclusion criteria:

Patients treated with multiple oral anticoagulants Taking multiple doses of the drug Taking drugs with indications other than prevention of stroke and hemorrhage Loss to follow-up before 1 year Patients without comorbidity known to be associated with higher mortality such as heart failure, cancer, chronic pulmonary disease

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **198**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using block randomization of 3 blocks in 3 groups including group A (Rivaroxaban), group B (Apixaban) and group C (Warfarin). According to the sample size, the number of these blocks is 66 (198/3). The block randomization are done by random number table at the beginning of the study and stored in a sealed envelope. After the research approval, the blocks will be taken out daily based on the patients' referrals through a person who is not in the study. Patients receive the desired drugs based on block permutation.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind randomized clinical trial in which neither the data analyst nor the person who is evaluating the outcomes knows which type of drugs patients are receiving until the end of the study .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan hospital

Street address

Farvardin Ave ., Ahvaz ., Iran

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Province

Khouzestan

Postal code

6135715794

Approval date

2022-02-01, 1400/11/12

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1400.174

Health conditions studied**1****Description of health condition studied**

Atrial fibrillation

ICD-10 code

I48.2

ICD-10 code description

Chronic atrial fibrillation

Primary outcomes**1****Description**

Minor and major bleeding

Timepoint

First after 6 months after 12 months

Method of measurement

Physical exam,Hemoglobin,Pletlet and Coagulation test

2**Description**

Ischemic stroke and Systemic embolism

Timepoint

First after 6 months after 12 months

Method of measurement

Physical exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 15-20 mg oral rivaroxaban once daily for 1 year (Arena Hayat Danesh company)

Category

Prevention

2

Description

Intervention group: 2.5-5 mg oral apixaban twice daily for 1 year (Arena Hayat Danesh company)

Category

Prevention

3

Description

Intervention group: 5 mg oral warfarin once daily for 1 year (Dr.Abidi pharmaceutical company)

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Zahra Khademi

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Recruitment center

Name of recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mehrnoosh Zakerkish

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Esfand Ave., Golestan Blvd ., Ahvaz., 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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Khademi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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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