Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Email address
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
City
Ahvaz
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

Street address

Azadegan Ave., Ahvaz ., Iran

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Phone

+98 61 3222 2922

Email

himam@ajums.ac.ir

2

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Zahra Khademi

Street address

Farvardin Ave ., Ahvaz ., Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135733118

Phone

+98 61 3320 4501

Email

golestanjpspital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr.Mehrnoosh Zakerkish

Street address

Esfand Ave., Golestan Blvd ., Ahvaz., Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3333 3477

Email

info@ajums.ac.ir

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
Street address
Esfand Ave., Golestan Blvd ., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3333 3477
Email
zahrakhademi157@gmail.com

Person responsible for scientific 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
Street address
Esfand Ave., Golestan Blvd ., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3333 3477
Email
zahrakhademi157@gmail.com

Person responsible for updating data

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
Street address
Esfand Ave., Golestan Blvd ., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3333 3477
Email
zahrakhademi157@gmail.com

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