

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparing efficacy of Rivaroxaban versus Warfarin on carotid plaque in NVAF patients

#### Protocol summary

##### Study aim

Determining and comparing the effectiveness of Rivaroxaban and Warfarin on carotid plaque in non-valvular atrial fibrillation patients

##### Design

This study is a 2-3 phase clinical trial in which 60 patients are divided into two groups. People who are visited on the even days receive Rivaroxaban and people who are visited on the odd days receive Warfarin. Patients follow for 6 months. Not blind, Two arm parallel groups, No control group

##### Settings and conduct

Sixty patients with non-valvular atrial fibrillation referred to Farabi hospital of Kermanshah in 1397 are randomly divided into two groups. One group will receive Rivaroxaban and one group will receive Warfarin

##### Participants/Inclusion and exclusion criteria

Non-valvular atrial fibrillation with stroke or transient ischemic attack or IF less than 30%, Lack of kidney and liver diseases and other specific disease, Not taking Aspirin

##### Intervention groups

One group will receive Rivaroxaban based on GFR and one group will receive Warfarin based on GFR

##### Main outcome variables

Carotid plaque size, Internal and common carotid stenosis grade, Create new carotid artery plaque, Stroke.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190729044372N1**

Registration date: **2019-09-01, 1398/06/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-01, 1398/06/10**

Update count: **0**

##### Registration date

2019-09-01, 1398/06/10

##### Registrant information

###### Name

Leila Afshar hezarkhani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8670 5503

###### Email address

lafsharh@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-07, 1397/12/16

##### Expected recruitment end date

2019-09-07, 1398/06/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing efficacy of Rivaroxaban versus Warfarin on carotid plaque in NVAF patients

##### Public title

Comparing efficacy of Rivaroxaban versus Warfarin on carotid plaque

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Non -valve atrial fibrillation with stroke or TIA or IF<30%

Not taking Aspirin Lack of kidney and liver diseases and other specific disease

**Exclusion criteria:**

Having a heart valve disorder Taking Aspirin

**Age**

No age limit

**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 Kermanshah University of Medical Sciences

**Street address**

Kermanshah University of Medical Sciences Building # 2, Shahidbeheshti Ave

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2019-01-08, 1397/10/18

**Ethics committee reference number**

IR.KUMS.REC.1398.183

## Health conditions studied

### 1

**Description of health condition studied**

Stroke

**ICD-10 code**

I67.9

**ICD-10 code description**

Cerebrovascular disease, unspecified

## Primary outcomes

### 1

**Description**

Carotid plaque size

**Timepoint**

Baseline and 6 months later

**Method of measurement**

Bilateral carotid artery color Doppler ultrasound

### 2

**Description**

Internal and common carotid stenosis grade

**Timepoint**

Baseline and 6 months later

**Method of measurement**

Bilateral carotid artery color Doppler ultrasound

### 3

**Description**

Create new carotid artery plaque

**Timepoint**

Baseline and 6 months later

**Method of measurement**

Bilateral carotid artery color Doppler ultrasound

## Secondary outcomes

### 1

**Description**

Brain stroke

**Timepoint**

At baseline and 6 Months later

**Method of measurement**

Bilateral carotid artery color Doppler ultrasound

### 2

**Description**

Probability of recurrence of stroke

**Timepoint**

At baseline and 6 Months later

**Method of measurement**

Bilateral carotid artery color Doppler ultrasound

## Intervention groups

### 1

**Description**

Intervention group: In this group, 30 patients are treated with Rivaroxaban based on GFR for 6 months.patients undergo Color Doppler ultrasound At baseline and after 6 months

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group:Thirty patients in this intervention group are treated for 6 months with warfarin made by Obeidi Company based on GFR. patients undergo Color Doppler ultrasound At baseline and after 6 months

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Farabi hospital

**Full name of responsible person**

Leila Afsharhezarkhani

**Street address**

Farabi hospital, Dolatabad Blvd, Isar Square, Kermanshsh

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

1336616351

**Phone**

+98 83 3836 1046

**Email**

Lafsharh@kums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

Deputy of Science and Technology, Kermanshah University of Medical Sciences,Shahid Beheshti Boulevard,Kermanshah

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**Fax**

+98 83 3837 0541

**Email**

farid\_n32@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Leila Afsharhezarkhani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

Farabi Hosital,Begining at Dolatabad Boulevard.Isar Sq

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Kermanshah University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Leila Afsharhezarkhani  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
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Lafsharh@kums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

All data is shared after unidentifiable people

### When the data will become available and for how long

Start of access period 6months after printing results

### To whom data/document is available

Dat will be available only to researchers working in academic and scientific institutions

### Under which criteria data/document could be used

For the people mentioned above there is no limit to how data will be used

### From where data/document is obtainable

Leila Afsharhezarkhani,lafsharh@kums.ac.ir

### What processes are involved for a request to access data/document

Contact with Leila Afsharhezarkhani via email (lafsharh@kums.ac.ir)

### Comments