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 wich 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 artrial 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)
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+98 21 8670 5503
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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 artrial fibrillation with stroke or TIA or IF<30%

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

Exclusion criteria:

Having a heart valve disorder Taking Asprin

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

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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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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

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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
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