Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

evaluation of the effect of rivaroxaban in comparison with warfarin in preventing deep vein thrombosis in patients with nephrotic syndrom

Protocol summary

Study aim

The effect of rivaroxaban on the prevention of deep vein thrombosis in patients with nephrotic syndrome
Evaluation of the effect of rivaroxaban in the prevention of deep renal vein thrombosis in patients with nephrotic syndrome

Design

In this study, 20 patients who are new cases of nephrotic syndrome are to be selected, which patients are divided into two groups of 10 non-selectively. This subject is designed as a double side open label randomized controlled trial

Settings and conduct

Patients are selected from Namazi and Faghihi hospitals and Motahhari clinic in Shiraz.The study is ambiguous and has no blinding

Participants/Inclusion and exclusion criteria

1.Newly diagnosed nephrotic syndrome (albumin less than 2.5 in a patient with MGN and albumin less than 2 in other cases of nephrotic syndrome) 2. The patient is between 18 and 60 years old 3. Absence of coagulation disorders 4. No active cancer 5. No pregnancy Do not be treated with aspirin or Plavix 7. Contraindications for possible use of anticoagulants 8. The risk of bleeding of the patient according to HAS-BLED criteria is low to medium risk 9. GFR greater than 60

Intervention groups

In this study, 20 patients who are new cases of nephrotic syndrome are divided into two groups of 10 non-selectively. One group is prevented with rivaroxaban at a dose of 10 mg daily and the other group is prevented with warfarin in the range (2≤INR≤3) (as a control group). This subject is designed as a double side open randomized controlled trial

Main outcome variables

1.Prevention of deep vein thrombosis of the lower extremities and kidneys with rivaroxaban 2. Thrombosis in the deep veins of the lower extremities and kidneys with rivaroxaban 3. Prevention of deep vein thrombosis of the lower extremities and kidneys with warfarin 4. Thrombosis in the deep veins of the lower extremities and kidneys with warfarin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220422054617N1**
Registration date: **2022-07-10, 1401/04/19**
Registration timing: **prospective**

Last update: **2022-07-10, 1401/04/19**
Update count: **0**

Registration date

2022-07-10, 1401/04/19

Registrant information

Name

Mitra Rasouli asl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 916 872 9856

Email address

arash.nik0000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of the effect of rivaroxaban in comparison with warfarin in preventing deep vein thrombosis in patients with nephrotic syndrom

Public title

the effect of rivaroxaban on the prevention of deep vein thrombosis in nephrotic syndrom

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Newly diagnosed nephrotic syndrome Albumin less than 2.5 in a patient with MGN Albumin less than 2 in other cases of nephrotic syndrome The age of the patient is between 18 and 60 years The patient's bleeding risk according to HAS-BLED criteria is low to moderate risk GFR greater than 60

Exclusion criteria:

coagulation disorders pregnancy active cancer taking aspirin taking plavix

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study is a random permutation block of four. The sampling method is that A represents the Case group (preventive with rivaroxaban drug) and B represents the control group (preventive with warfarin drug). The number of different situations is six as follows. It is ABBA, BAAB, BBAA, AABB, ABAB, BABA. We assign a number to each of these states. By using the table of random numbers, a list of twenty people (five blocks of four) is produced.

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 Shiraz University of Medical Sciences

Street address

No. 8, the first alley of Farhangian alley, Telemim street

City

behbahan

Province

Khouzestan

Postal code

6361983131

Approval date

2022-04-03, 1401/01/14

Ethics committee reference number

IR.SUMS.MED.REC.1401.010

Health conditions studied

1

Description of health condition studied

Nephrotic syndrom

ICD-10 code

N04

ICD-10 code description

Nephrotic syndrome

Primary outcomes

1

Description

Deep vein thrombosis after taking rivaroxaban

Timepoint

At the beginning of the study and once every three months

Method of measurement

Color Doppler ultrasound of the deep veins of the lower extremities and renal arteries

Secondary outcomes

empty

Intervention groups

1

Description

Control group: prophylaxis with warfarinTen patients are treated with warfarin as a control group and at the beginning of the study and once every three months until the albumin is less than 2.5, they undergo color Doppler ultrasound of deep renal veins and lower extremities. The number range is 2 to 3

Category

Prevention

2

Description
Intervention group: under prevention with rivaroxabanAnother 10 patients are prevented with Rivaroxaban 10 mg orally daily and at the beginning and once every three months undergo deep calorie doppler ultrasound. Both groups are prevented with drug and sonography until the albumin is less than 2.5 they take
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi and Shahid Faghihi Hospital and Motahhari Clinic
Full name of responsible person
Maryam Shafiee
Street address
Namazi hospital
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.....
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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City
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Fax
Email
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Shafiee
Position
Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Nephrology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data can potentially be shared after not identifying individuals

When the data will become available and for how long

One month after printing the results

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

No special conditions are required

From where data/document is obtainable

Arash.nik0000@gmail.com

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

Request by email

Comments