

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 ( $2 \leq \text{INR} \leq 3$ ) (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

Khuzestan

##### 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 syndrom

## 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 warfarin Ten 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 rivaroxaban Another 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

##### City

Shiraz

##### Province

Fars

##### Postal code

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##### Phone

+98 916 872 9856

##### Email

Arash.nik0000@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mahtab Memarpour

##### Street address

Zand

##### City

Shiraz

##### Province

Fars

##### Postal code

.....

##### Phone

+98 916 872 9856

##### Fax

##### Email

Arash.nik0000@gmail.com

##### 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

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Namazi hospital.zand

#### City

Shiraz

#### Province

Fars

#### Postal code

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#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Mitra Rasouli asl

#### Position

Resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Internal Medicine

#### Street address

No. 8, Farhangian Alley, 1st Alley, Farhangian Alley

#### City

Shiraz

#### Province

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**Postal code**  
6361983131  
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**Email**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Mitra Rasouli asl  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Nephrology  
**Street address**  
No. 8, Farhangian Alley, 1st Alley, Farhangian Alley  
**City**  
Behbahan  
**Province**  
Khouzestan  
**Postal code**  
6361983131  
**Phone**  
+98 61 5272 0315  
**Email**  
Arash.nik0000@gmail.com

## 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