# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jun 2026

## Effect of rivaroxaban versus apixaban on treatment of cerebral venous thrombosis: a randomized clinical trial

### Protocol summary

**Study aim**
To assess the effect of rivaroxaban versus apixaban on treatment of cerebral venous thrombosis

**Design**
This is a randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the block randomization to the intervention and control groups

**Settings and conduct**
This study will be performed in the Besat Hospital in Hamadan city on 32 eligible patients. The patients will be randomly assigned to the intervention and control groups through the block randomization. This study will be performed without blinding.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age 18 to 80 years Cerebral venous thrombosis Exclusion criteria: Contraindication o anticoagulant therapy Brain tumor

**Intervention groups**
Intervention group: Rivaroxaban tablets 15 mg twice a day for 3 weeks and then 20 mg daily for 6 months Control group: Apixaban tablets 10 mg twice a day for 3 weeks and then 5 mg twice a day for 6 months

**Main outcome variables**
Primary outcome: Functional impairment Secondary outcome: Complication of cerebral hemorrhage

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120215009014N451**
Registration date: **2022-12-24, 1401/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-24, 1401/10/03**
Update count: **0**

**Registration date**
2022-12-24, 1401/10/03

**Registrant information**
**Name**
Jalal Poorolajal
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-12-22, 1401/10/01

**Expected recruitment end date**
2023-09-22, 1402/06/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Effect of rivaroxaban versus apixaban on treatment of cerebral venous thrombosis: a randomized clinical trial

**Public title**
Effect of rivaroxaban versus apixaban on treatment of cerebral venous thrombosis

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
**Inclusion criteria:**

Age 18 to 80 years Cerebral venous thrombosis

**Exclusion criteria:**

Contraindication o anticoagulant therapy Brain tumor

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

**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 Hamadan University of Medical Sciences

**Street address**

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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**Approval date**

2022-06-27, 1401/04/06

**Ethics committee reference number**

IR.UMSHA.REC.1401.321

## Health conditions studied

### 1

**Description of health condition studied**

Cerebral venous thrombosis

**ICD-10 code**

I63.00

**ICD-10 code description**

Cerebral infarction due to thrombosis of unspecified precerebral artery

## Primary outcomes

### 1

**Description**

Functional impairment

**Timepoint**

90 days after intervention

**Method of measurement**

Using modified Rankin Scale (mRS)

## Secondary outcomes

### 1

**Description**

Complication of cerebral hemorrhage

**Timepoint**

During the 6-month follow-up period

**Method of measurement**

Using brain CT scan

## Intervention groups

### 1

**Description**

Intervention group: Rivaroxaban tablets 15 mg twice a day for 3 weeks and then 20 mg daily for 6 months

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Apixaban tablets 10 mg twice a day for 3 weeks and then 5 mg twice a day for 6 months

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Besat Hospital in Hamadan city

**Full name of responsible person**

Dr Maryam Ghasemi

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## Sponsors / Funding sources

**1**

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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**
Hamedan 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**
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Hamedan University of Medical Sciences
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## Person responsible for updating data

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## 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