

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating the efficacy and safety of rivaroxaban comparing to warfarin in patients with chronic thromboembolic pulmonary hypertension (CTEPH) following endarterectomy surgery

#### Protocol summary

##### Study aim

Main Objectives: rate of re-thrombosis, hemorrhagic stroke, ischemic stroke with rivaroxaban in comparison with warfarin in CTEPH patients undergoing endarterectomy

##### Design

A parallel clinical trial with a control group, with phase 2 randomized parallel groups on 96 patients. [www.sealedenvelope.com](http://www.sealedenvelope.com) was used for randomization.

##### Settings and conduct

Patients with chronic thromboembolic pulmonary hypertension who underwent endarterectomy at Masih Daneshvari Hospital will be evaluated for any re-thrombosis, hemorrhagic and ischemic stroke, readmission and bleeding at intervals of one, three and six months.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who underwent endarterectomy after chronic pulmonary hypertension thromboembolic in Masih Daneshvari Hospital. Exclusion criteria: Any allergy to the prescribed drug, any bleeding including active gastrointestinal, pulmonary, urogenital bleeding, cerebral aneurysm, cerebral hemorrhage, aneurysm and aortic dissection, patient undergoing spinal puncture, dyscrasia, uncontrolled blood pressure (Pressure <110/180 mmHg), inflammation and effusion of the pericardium, bacterial endocarditis, pregnancy and lactation, liver disease (child pugh B&C), GFR <30 mL/min, any coagulation disorders, if the patient has strong Cyp450 and Pgp inhibitors such as ketoconazole, Itracenazole, posaconazole and ritonavir are prescribed.

##### Intervention groups

A total of 96 patients with CTEPH who underwent endarterectomy at Masih Daneshvari Hospital are randomly selected and studied in a warfarin-treated control group of 65 and rivaroxaban-treated intervention group of 35 patients.

#### Main outcome variables

Primary Outcomes: The incidence of recurrent thrombosis, ischemic stroke and hemorrhagic stroke are considered as primary outcomes.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151227025726N22**

Registration date: **2020-10-07, 1399/07/16**

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

Last update: **2020-10-07, 1399/07/16**

Update count: **0**

##### Registration date

2020-10-07, 1399/07/16

##### Registrant information

##### Name

Farzaneh Dastan

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 270 5933

##### Email address

f\_dastan@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-08, 1398/07/16

##### Expected recruitment end date

2020-12-06, 1399/09/16

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the efficacy and safety of rivaroxaban comparing to warfarin in patients with chronic thromboembolic pulmonary hypertension (CTEPH) following endarterectomy surgery

**Public title**

Evaluating the efficacy and safety of rivaroxaban comparing to warfarin in patients with chronic thromboembolic pulmonary hypertension (CTEPH) following endarterectomy surgery

**Purpose**

Treatment

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

Patients undergoing endarterectomy following chronic thromboembolic pulmonary hypertension at Masih Daneshvari Hospital.

**Exclusion criteria:**

Any allergies to the prescribed medication Any bleeding includes active gastrointestinal, pulmonary, genitourinary bleeding Cerebral aneurysm Intracranial bleeding Aneurysm and aortic dissection A patient undergoing spinal puncture Blood dyscrasia Uncontrolled blood pressure (110/180 mmHg <pressure) Inflammation and pericardial effusion Bacterial endocarditis Pregnancy and lactation Liver disease(child pugh B&C) GFR<30 mL/min Any coagulation disorder If the patient has been prescribed strong Cyp450 and Pgp inhibitors such as ketoconazole, itraconazole, posaconazole and ritonavir.

**Age**From **18 years** old to **80 years** old**Gender**

Both

**Phase**

2-3

**Groups that have been masked***No information***Sample size**Target sample size: **96****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method was used in this study. Using online randomiser website ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)), patients were randomised with 1-2 ratio into two groups.

**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 Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti School of Pharmacy, No 2660, Niayesh intersection, Valiasr St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1991953381

**Approval date**

2019-10-07, 1398/07/15

**Ethics committee reference number**

IR.SBMU.PHARMACY.REC.1398.175

**Health conditions studied****1****Description of health condition studied**

Chronic Thrombo Embolic Pulmonary Hypertension(CTEPH)

**ICD-10 code**

I27. 24

**ICD-10 code description**

Chronic Thromboembolic Pulmonary Hypertension.

**Primary outcomes****1****Description**

Recurrence of thrombosis

**Timepoint**

Patients are evaluated at one, three and six months after surgery.

**Method of measurement**

Medical record

**2****Description**

Incidence of ischemic and hemorrhagic stroke

**Timepoint**

Patients are evaluated at one, three and six months after surgery.

**Method of measurement**

Medical record

## Secondary outcomes

### 1

#### Description

Incidence of bleeding

#### Timepoint

Patients are evaluated at intervals of one, three and six months after surgery.

#### Method of measurement

Medical record

### 2

#### Description

Patient readmission

#### Timepoint

Patients are evaluated at intervals of one, three and six months after surgery.

#### Method of measurement

Medical record

## Intervention groups

### 1

#### Description

Intervention group: For the intervention group, rivaroxaban was prescribed at a dose of 15 mg twice a day for 21 days and then 20 mg once a day. In the study, Rivaroxaban made by Dr. Abidi Pharmaceutical Company under the brand name Xalerban will be used.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Apotex warfarin tablet will be prescribed based on patients INR goal of 2-3.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Masih Daneshvari Hospital

##### Full name of responsible person

Farzaneh Dastan

##### Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

##### City

Tehran

##### Province

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##### Postal code

1956944413

##### Phone

+98 21 2712 3000

#### Email

F\_Dastan@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hassan Yazdan Panah

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Shahid Beheshti School of Pharmacy, No 2660, Niayesh intersection, Valiasr St.

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#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Hossein Amini Ebrahimabad

##### Position

pharmacy student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Medical Pharmacy

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Farzaneh dastan  
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assistant professor  
**Latest degree**  
Specialist  
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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences  
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pharmacy student  
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Hosseinamini96@yahoo.com

## 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

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

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

All potential data can be shared after blinding

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

Six months after publishing the results

### To whom data/document is available

Researchers working in academic institutions

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

For research purposes and meta-analysis studies

### From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,  
Daar-Abad, Niavaran

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

Official letter to the researchers

### Comments