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 endartrectomy 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 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 endartrectomy surgery

Public title
Evaluating the efficacy and safety of rivaroxaban comparing to warfarin in patients with chronic thromboembolic pulmonary hypertension (CTEPH) following endartrectomy 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), 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, Rivaoxaban 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
Tehran
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
Street address
Shahid Beheshti School of Pharmacy, No 2660, Niayesh intersection, Valiasr St.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
MPD@sbmu.ac.ir
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
Street address
Shahid Beheshti School of Pharmacy, No 2660, Niayesh intersection, Valiasr St.
City
Tehran

Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
Hosseinamini96@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh dastan
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Shahid Beheshti School of Pharmacy, No 2660, Niayesh intersection, Valiasr St.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
F_dastan@sbmu.ac.ir

Person responsible for updating data

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
Street address
Shahid Beheshti School of Pharmacy, No 2660, Niayesh intersection, Valiasr St.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
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