Clinical Trial Protocol
Iranian Registry of Clinical Trials
18 Oct 2022

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 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, Itarcnazole, 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

Registrant information
Name
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Name of organization / entity
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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
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

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
Masah Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan
Street address
Dr. Masah Daneshvari Hospital, Daar-Abad, Niavaran
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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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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
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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, Na'avan
What processes are involved for a request to access data/document
Official letter to the researchers
Comments