Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Comparison of rivaroxaban and enoxaparin in the prevention of recurrent venous thromboembolism in patients with nonhematologic cancer

Protocol summary

Study aim

Comparison of rivaroxaban and enoxaparin in the prevention of recurrent venous thromboembolism in patients with nonhematologic cancer.

Design

The present study is a clinical trial of phase 3, randomized, double-blind, and parallel, which will be carried out on 50 patients with non-hematologic cancer with venous thromboembolism. Patients are randomly divided into two groups receiving enoxaparin or rivaroxaban.

Settings and conduct

The present study is a double-blind clinical trial with the aim of Determining and comparing the frequency of recurrent thromboembolism (pulmonary thromboembolism and deep vein thrombosis) in patients with nonhematologic cancer with venous thromboembolism in two groups based on patient characteristics (before and after treatment) at Imam Khomeini Hospital, Ahvaz. Physician, researcher, patient, and data analyst is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Including criteria: Existence of active cancer with Venous thromboembolism; The age range is between 18-75 years; Tendency to participate in the study; Exclusion criteria: Smoking, alcohol, and drug abuse; Lack of sufficient and appropriate evidence for the occurrence of early Venous thromboembolism; Diagnosis of thrombophilic conditions; Prescribe any anticoagulant drug excepting Enoxaparin or Rivaroxaban (for example Heparin, Warfarin, Dabigatran, Apixaban, and Edoxaban)

Intervention groups

Treatment with Rivaroxaban: 15 mg every 12 hours for the first three weeks and then 20 mg daily. Treatment with Rivaroxaban: Dose 1 mg per kg body weight, by subcutaneous injection every 12 hours

Main outcome variables

frequency of recurrent thromboembolism (pulmonary thromboembolism and deep vein thrombosis)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201123049469N1**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**
Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Afrooz Kargaran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 4578

Email address

karegaran.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of rivaroxaban and enoxaparin in the prevention of recurrent venous thromboembolism in patients with nonhematologic cancer

Public title
Comparison of rivaroxaban and enoxaparin in the prevention of recurrent venous thromboembolism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of active cancer with Venous thromboembolism The age range is between 18-75 years Tendency to participate in the study
Exclusion criteria:
Smoking, alcohol and drug abuse Lack of sufficient and appropriate evidence for the occurrence of early Venous thromboembolism Diagnosis of thrombophilic conditions Prescribe any anticoagulant drug excepting Enoxaparin or Rivaroxaban (for example Heparin, Warfarin, Dabigatran, Apixaban, and Edoxaban)
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Permuted block randomization; Randomization unit: Person; Stratified randomization: Not done; Randomization instrument: Random allocation software (Excel); Random sequence generation: Used random blocks, each block containing 4 people and allocated a number from 1 to 6 to each block; Allocation concealment: The randomization process is performed by the study methodology consultant and, clinical researchers are not aware of the randomization process.
Blinding (investigator's opinion)
Double blinded
Blinding description
The type of blindness in our study will be double-blind. Prior to the onset of the study, the box containing the relevant tablets are coded A and B by someone except the researcher, in order to blind the researcher about which drug each group received. When delivering drugs to patients, someone except the researcher should locate the patient in either A or B group by random number table. In this study, the patient, physician, and researcher (who collecting data and assessing the outcome) should be kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2019-12-28, 1398/10/07
Ethics committee reference number
IR.AJUMS.REC.1398.699

Health conditions studied

1

Description of health condition studied
Nonhematologic Cancers
ICD-10 code
I74.9
ICD-10 code description
Embolism and thrombosis of unspecified artery

Primary outcomes

1

Description
Recurrence of VTE (Venous thromboembolism) is deep vein thromboembolism (DVT) or pulmonary embolism (PE) according to the report of CT scan of the pulmonary arteries and color Doppler ultrasound of the lower extremity to be reported by the radiologist.
Timepoint
At the beginning of the study (before the intervention) and 6 months later
Method of measurement
according to the report of CT scan of the pulmonary arteries and color Doppler ultrasound of the lower extremity to be reported by the radiologist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Oral rivaroxaban treatment group, 15 mg every 12 hours for the first three weeks and then 20 mg daily / Axabin; Abidi Company, Tehran
Category
Treatment - Drugs

2

Description
Intervention group: The dose of enoxaparin (Lovenox; Osweh Pharmacy, Tehran) was 1 mg per kg body weight, but because 60 or 80 mg ampoules were used, depending on the patient's weight, 60 or 80 mg of the drug every 12 hours as the following injection It was prescribed cutaneously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Afrooz Kargaran Dehkordi
Street address
Imam Khomeini Hospital,Azadegan Ave, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
+98 61 3321 4578
Email
karegaran.a@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Vice Chancellor for Research and Technology,Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 7570
Fax
+98 61 3336 1544
Email
badavi-m@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Afrooz Kargaran Dehkordi
Position
Resident of Internal Medicine
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Imam Khomeini Hospital,Azadegan Ave, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
+98 61 3321 4578
Email
karegaran.a@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person
Afrooz Kargaran Dehkordi

Position
Resident of Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Afrooz Kargaran Dehkordi

Position
Resident of Internal Medicine

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Internal Medicine

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Email
karegaran.a@ajums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
If the decision is to publicate the data, after the unidentified individuals all data will be publicated.

When the data will become available and for how long
The access period will be 8 months after the publication of the results.

To whom data/document is available
Researchers working in academic and industrial institutions can apply to get data.

Under which criteria data/document could be used
To cite. Referring to reference or researcher's permission

From where data/document is obtainable
Afrooz Kargaran Dehkordi, Resident of Internal Medicine, Imam Khomeini Hospital,Azadegan Ave, Ahvaz./ +98 61 3321 4578/ karegaran.a@ajums.ac.ir

What processes are involved for a request to access data/document
Access to articles related to this research Send email to the responsible author

Comments