

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Afroz Kargar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3321 4578

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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		Assignment Parallel
		Other design features
Public title	Comparison of rivaroxaban and enoxaparin in the prevention of recurrent venous thromboembolism	Secondary Ids empty
Purpose	Treatment	Ethics committees
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)	1
Age	From 18 years old to 75 years old	Ethics committee
Gender	Both	Name of ethics committee Ethics committee of Ahvaz University of Medical Sciences
Phase	3	Street address Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor	City Ahvaz
Sample size	Target sample size: 50	Province Khouzestan
Randomization (investigator's opinion)	Randomized	Postal code 6135715794
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.	Approval date 2019-12-28, 1398/10/07
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number IR.AJUMS.REC.1398.699
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.	Health conditions studied
Placebo	Not used	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

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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

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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

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

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Person responsible for updating data

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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