

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of Enoxaparin versus oral Rivaroxaban in prevention of deep vein thrombosis in patients admitted to intensive care unit

Protocol summary

Study aim

Comparison of Enoxaparin versus oral Rivaroxaban in prevention of deep vein thrombosis in patients admitted to intensive care unit

Design

This study is clinical trial and single blind.98 patients in ICU in Valiasr Hospital in Arak will inter this study.We will divide patients in 2 groups by simple randomization.Groups are parallel.

Settings and conduct

This study is clinical trial and single blind.98 patients will inter this study.Outcome assessor and analyzer don't aware from grouping.Groups A and B are available to analyzer and outcome assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages 18 to 60 years, gavage or beginning of oral feeding, glomerular filtration above 50% Exclusion criteria: contraindications to anti-coagulant, allergy to Rivaroxaban

Intervention groups

Intervention group: We treat patients with 15 milligram Rivaroxaban tablets once in day orally or gavage until they have the order to get out of bed. Control group: We treat patients with 40 milligram Enoxaparin once day subcutaneously until they have the order to get out of bed.

Main outcome variables

Incidence of thromboembolism

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N140**

Registration date: **2020-04-08, 1399/01/20**

Registration timing: **retrospective**

Last update: **2020-04-08, 1399/01/20**

Update count: **0**

Registration date

2020-04-08, 1399/01/20

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Enoxaparin versus oral Rivaroxaban in prevention of deep vein thrombosis in patients admitted to intensive care unit

Public title

Comparison of two kind of drug oral and subcutaneous in prevention of deep vein thrombosis in patients admitted to intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ages 18 to 60 years Possibility to gavage or start oral feeding Glomerular filtration above 50% Patients hospitalized in intensive care units

Exclusion criteria:
Contraindications to anti-coagulant Allergy to Rivaroxaban

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization will be used with envelopes in two groups A and B. In this method, we will select a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards will be shuffled. One card will be taken out and its allocation is registered and the card was returned to the other cards after leaving. Then the cards are shuffled again and we will take another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-10-21, 1397/07/29

Ethics committee reference number

IR.ARAKMU.REC.1397.189

Health conditions studied

1

Description of health condition studied

Thromboembolism

ICD-10 code

O88.23

ICD-10 code description

Embolism and thrombosis of unspecified artery

Primary outcomes

1

Description

Incidence of thromboembolism

Timepoint

After the end of treatment

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We treat patients with 15 milligram Rivaroxaban tablets daily orally or oral gavage until they have the order to get out of bed.

Category

Treatment - Drugs

2

Description

Control group: We treat patients with 40 milligram Enoxaparin ampule daily subcutaneously until they have the order to get out of bed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Behnam Mahmodie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Behnam Mahmodie

Position

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Alikhani

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

Yes - There is 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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Behnam Mahmoudie

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

They have to write letters to the professors and the university

Comments