

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Survey of Low-dose Heparin, Enoxaparin and Rivaroxaban as Prophylaxis against Venous Thromboembolism in Moderate to Severe Traumatic Brain Injury: A Randomized Clinical Trial Study

Protocol summary

Study aim

Determining the preventive effect of enoxaparin, heparin and rivaroxaban drugs on venous thromboembolic events in patients with moderate to severe traumatic brain injury

Design

An uncontrolled clinical trial, parallel-group, triple-blind, randomized, phase 2, on 60 patients. Six permutation blocks will be used for randomization.

Settings and conduct

Basic characteristics and history of diseases are recorded. Patients are prescribed the first dose of heparin, enoxaparin and rivaroxaban after 48 hours from the time of trauma in Imam Reza (AS) Birjand Hospital. CT scan of the brain will be performed six hours after administration of the first dose of drug prophylaxis and then on day 4 and then before discharge. The anticonvulsant will be levotirastam. Lower Doppler ultrasound will be performed within 24 hours of admission and also at the time of discharge or ten days after the trauma.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 16 to 70 with non-penetrating head trauma Exclusion criteria: Patients who have any type of coagulopathy and do not have the conditions to receive anticoagulants

Intervention groups

1- Heparin recipient group 2- Enoxaparin receiving group 3- Rivaroxaban recipient group

Main outcome variables

1-Age 2-sex 3-Weight 4-Type of prescription drug 5-Mechanism of head injury 6-GCS before admission 7-GOS 8-Vital signs 9-AIS 10Hospitalization period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230705058684N1**

Registration date: **2023-08-01, 1402/05/10**

Registration timing: **prospective**

Last update: **2023-08-01, 1402/05/10**

Update count: **0**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Mohammadhosain Afrand

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3721 7280

Email address

hosain.afrand@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-04-03, 1403/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of Low-dose Heparin, Enoxaparin and

Rivaroxaban as Prophylaxis against Venous Thromboembolism in Moderate to Severe Traumatic Brain Injury: A Randomized Clinical Trial Study		Secondary Ids	
		empty	
Public title		Ethics committees	
Low-dose Heparin, Enoxaparin and Rivaroxaban as Prophylaxis against Venous Thromboembolism in Moderate to Severe Traumatic Brain Injury		<u>1</u>	
Purpose		Ethics committee	
Prevention		Name of ethics committee	
Inclusion/Exclusion criteria		Ethics committee of Birjand University of Medical Sciences	
Inclusion criteria:		Street address	
Moderate to Severe Traumatic Brain Injury Age between 16 and 70 Latency time between injury and entering the study of less than 6 h Without history of coagulopathy Caprini Score of 3 or greater Closed head injury Glasgow Coma Scale (GCS) between 3 and 13 AIS (Abbreviated Injury Score 3 or less than 3		Taleghani Ave., Emam Reza (AS) Hospital, Birjand, Southern Khorasan Province, Iran	
Exclusion criteria:		City	
		Birjand	
Age		Province	
From 16 years old to 70 years old		South Khorasan	
Gender		Postal code	
Both		8917145438	
Phase		Approval date	
2		2023-07-03, 1402/04/12	
Groups that have been masked		Ethics committee reference number	
• Participant • Care provider • Investigator • Outcome assessor • Data analyser • Data and Safety Monitoring Board		IR.BUMS.REC.1402.170	
Sample size		Health conditions studied	
Target sample size: 60		<u>1</u>	
Randomization (investigator's opinion)		Description of health condition studied	
Randomized		Moderate to Severe Traumatic Brain Injury	
Randomization description		ICD-10 code	
Random allocation is done using 6 permutation blocks, individually and by a sealed envelope.		S00-S09	
Blinding (investigator's opinion)		ICD-10 code description	
Triple blinded		Injuries to the head	
Blinding description		Primary outcomes	
Due to the low level of consciousness, the patients do not know about the type of medicine they received (due to the fact that all three drugs are common in preventing the intended outcome in the study, it does not create a problem from an ethical point of view). According to the randomization of the sampling of 6 substitution type, the healthcare personnel and the doctor in charge of the patient are not involved in the choice of medicine and are blinded. The person in charge of data collection did not interfere in the selection of the drug for the reasons mentioned, and blinding was done.		<u>1</u>	
Placebo		Description	
Not used		DVT	
Assignment		Timepoint	
Parallel		Lower Doppler ultrasound will be performed within 24 hours of admission to determine the presence of DVT before or at the time of admission, as well as at the time of discharge or ten days after trauma (the highest incidence of thromboembolism in trauma patients) or based on the indication and diagnosis of the therapist (in case of suspicion of thromboembolism based on symptoms). DVT diagnosis will be done with Doppler ultrasound and with ultrasound of the popliteal, saphenous, femoral and iliac veins.	
Other design features		Method of measurement	
		DVT diagnosis will be done with Doppler ultrasound and with ultrasound of the popliteal, saphenous, femoral and iliac veins.	
		<u>2</u>	
		Description	

PE
Timepoint
Diagnosis of PE will be done with spiral CT angiography of the lungs and if indicated.
Method of measurement
Spiral CT angiography of the lungs

Secondary outcomes

1

Description
Glasgow coma scale between 3 and 13
Timepoint
Daily
Method of measurement
Clinical condition of the patient

2

Description
Intracranial Hematoma
Timepoint
According to the clinical presentation
Method of measurement
Brain CT- Scan

Intervention groups

1

Description
Intervention group: Heparin receiving group
Category
Prevention

2

Description
Intervention group: Enoxaparin receiving group
Category
Prevention

3

Description
Intervention group: Rivaroxaban receiving group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza (AS) Hospital
Full name of responsible person
Mohammadhosain Afrand
Street address
Taleghani
City

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8917145438
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+98 56 3162 4000
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Hosain.afrand@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Reza Miri
Street address
Birjand University of Medical Sciences , Ghafari Street, Birjand, South Khorasan, Iran.
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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
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Mohammadhosain Afrand
Position
Resident of Neurosurgery
Latest degree
Medical doctor

Other areas of specialty/work

Neurosurgery

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Fax**Email**

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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

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

All statistical information will be available without limitation

From where data/document is obtainable

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

They will receive the data by email to the person in charge of the project

Comments