Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Investigating the effectiveness of anticoagulants compared to aspirin and clopidogrel on disease severity in patients with ischemic stroke.

Protocol summary

Study aim

Investigation of anticoagulants with aspirin and clopidogrel on disease severity in patients with non-embolic ischemic stroke.

Design

86 patients with ischemic stroke without embolism were divided into two groups by block randomization method. One group will receive enoxaparin then rivaroxaban and the other group will receive aspirin and clopidogrel. The researcher is blind to the studied groups. Patients will be examined 10 days later and 3 months later with NIHSS and MRS criteria for disability and clinical status.

Settings and conduct

Study subjects are randomly divided into two groups. One group of enoxaparin with a therapeutic dose (one mg per body weight) in the first 24 hours and then on the second day of starting rivaroxaban with a dose of 20 mg along with enoxaparin 40 mg daily is prescribed, and the other group is prescribed aspirin 80 and clopidogrel 75 from They will receive at the very beginning. These interventions are performed in the neurology department of Imam Hassan Bejnoord Hospital

Participants/Inclusion and exclusion criteria

Patients with ischemic stroke without embolic origin aged between 18 and 90 years after CT scan and ECG and using the NIHSS scoring criteria (patients with a score of less than 15) were randomized with the onset of symptoms in the first 24 hours. They are included in the study by specialized random block method.

Intervention groups

One group will be prescribed enoxaparin with a therapeutic dose in the first 24 hours and then on the second day of starting rivaroxaban along with daily enoxaparin, and the other group will receive aspirin and clopidogrel from the beginning.

Main outcome variables

Patients will be evaluated 10 days later and 3 months later with NIHSS and MRS for disability and clinical status, respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221026056307N1**
Registration date: **2023-01-18, 1401/10/28**
Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**
Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Hasan Namdar Ahmadabad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 58 3151 3001

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of anticoagulants compared to aspirin and clopidogrel on disease severity in patients with ischemic stroke.

Public title
Investigating the effectiveness of anticoagulants compared to aspirin and clopidogrel on disease severity in patients with ischemic stroke.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with ischemic stroke without embolic origin Patients aged 18 to 90 years NIHSS less than 15

Exclusion criteria:
Patients with hemorrhagic stroke Patients with ischemic stroke of embolic origin Stroke patients with NIHSS scores less than 15

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, due to the fact that two tablets (aspirin and clopidogrel) will be used in one group and one tablet and one ampoule (rivaroxaban and enoxaparin) will be used in the other group, complete blinding is not possible. Because the researchers do not want to use additional and unnecessary injections for blinding. For this purpose, a research assistant (for example, a neurology department nurse) who is not blind will be used to prescribe drugs. But the treating doctor and the analyst will not be aware of the drugs received by the patient

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of North Khorasan University of Medical Sciences

Street address
Immam Hasan Hospital, Arkan Blvd, Bojnurd,

City
Bojnurd

Province
North Khorasan

Postal code
7487794149

Approval date
2022-08-28, 1401/06/06

Ethics committee reference number
IR.NKUMS.REC.1401.033

Health conditions studied

1

Description of health condition studied
Cerebral infarction

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
MRS scores

Timepoint
10 days and 3 months after the intervention

Method of measurement
MRS is a commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke or other causes of neurological disability.A score of 0 is no disability, 5 is disability requiring constant care for all needs; 6 is death.

2

Description
NIHSS scores

Timepoint
10 days and 3 months after the intervention

Method of measurement
The NIHSS is composed of 11 items, each of which scores a specific ability between a 0 and 4. For each item, a score of 0 typically indicates normal function in that specific ability, while a higher score is indicative of some level of impairment.The individual scores from each item are summed in order to calculate a patient's total NIHSS score. The maximum possible score is 42, with the minimum score being a 0.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: An enoxaparin group with a therapeutic dose (one mg per body weight) is prescribed in the first 24 hours and then on the second day of starting rivaroxaban with a dose of 20 mg along with enoxaparin 40 mg daily from the beginning and will receive it for 10 days.
Category
Treatment - Drugs

2

Description
Intervention group: The other group will receive aspirin 80 mg and clopidogrel 75 mg from the beginning and will receive it for 10 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hassan Hospital
Full name of responsible person
Amir Ali Ghahramani
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Imam Hassan Hospital, Arkan Blv. Bojnurd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
Mohammad Amin Yunsi
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Vice President of Research and Technology of North Khorasan University of Medical Sciences, Blv.Shahriar, Bojnurd
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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
Bojnourd 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
Bojnourd University of Medical Sciences
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Amir Ali Ghahramani
Position
Assistant Professor
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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
The data is expected to be published in 2023
When the data will become available and for how long
The data is expected to be published in 2023
To whom data/document is available
public
Under which criteria data/document could be used
Research projects have been developed
From where data/document is obtainable
Dr.Amirali Ghahramani
What processes are involved for a request to access data/document
Application from North Khorasan University of Medical Sciences
Comments