

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

Full name of responsible person

Amir Ali Ghahramani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Latest degree

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Other areas of specialty/work

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Province

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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