

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effectiveness of "prescribing Fingolimod with Non-prescribing fingolimod in improving stroke related scales in Acute Ischemic Stroke(AIS) patients referring in 4.5 hours of symptoms onset

Protocol summary

Study aim

Comparison of the effectiveness of "prescribing Fingolimod with Non-prescribing fingolimod in improving stroke related scales in Acute Ischemic Stroke(AIS) patients referring in 4.5 hours of symptoms onset

Design

A double blind, randomized, parallel group phase 2-3 trial design of 50 patients, whom will be enrolled between may 2022 and July 2022, and will be followed for 6 months.

Settings and conduct

Patients, who are suspected of acute ischemic stroke, referring to emergency ward of Tehran's Shariati hospital who have acute neurologic deficits with NIHSS more than 6 and no ICH in entrance brain CT and no exclusion criteria will be divided in two arms whom both get a standard stroke care receiving fingolimod in one and placebo in another by random thereby assessing in determined times. The pharmaceutical intermediary will give medicine and placebo as group A and B to the researcher(blinded); afterwards, the researcher will inform the prescribing physician(blinded) the A or B group on the basis of 2*2 blocked randomization; at last, patients will be assessed at entrance, 1month and 6 months later by assessing physician(blinded).

Participants/Inclusion and exclusion criteria

Patients with acute onset focal neurologic deficit with Age more than 18 years who referring to hospital in less than 4.5 hours: excluded by major heart retinal problems, age more than 80 or whom have ICH in entrance CT-scan

Intervention groups

In the first group , patients will get routine standard care including thrombolysis in conjunction with fingolimod , as a neuroprotective drug, for assessing whether there is an efficacy in determined time windows . simultaneously, control group will get the same care except fingolimod.

Main outcome variables

NIHSS and MRS scale in 0, 1, 6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220423054619N1**

Registration date: **2022-05-29, 1401/03/08**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-29, 1401/03/08**

Update count: **0**

Registration date

2022-05-29, 1401/03/08

Registrant information

Name

Hamed Shahriyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7671 0756

Email address

hamedshahriyari69@icloud.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of "prescribing Fingolimod with Non-prescribing fingolimod in improving stroke related scales in Acute Ischemic Stroke(AIS) patients referring in 4.5 hours of symptoms onset

Public title
Effect of Fingolimod in acute ischemic stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute onset focal neurologic deficit Age more than 18 years referring to hospital in less than 4.5 hours

Exclusion criteria:

Age more than 80 History of moderate or severe cardiovascular condition History of prior probable retinal problems Active viral or bacterial infection Suspicion of other neurologic conditions than CVA No existing hyperdense lesion in entry CT scan consisting with hemorrhagic lesion

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Firstly, Randomization is performing in 2*2 blocking in individualized manner using "Random Allocation" software. Afterwards, placebo and medication consign to blinded researcher by an intermediary as group A and B. At last, Researcher will allocate the medication or placebo to the first line physicians of trial to prescribe them for enrolled patients, whom are blinded, based on the determined randomized blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
Firstly, the researcher receive two groups of placebo and real medication in similar form, then the assessor physician will evaluate the patients without any information of the patient's assigned group; finally, the analysisist do the analysis just based on the two groups without prior knowledge

Placebo
Used

Assignment

Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran university of medical sciences, Poursina street

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Tehran

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Tehran

Postal code

1417613151]

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.599

Health conditions studied

1

Description of health condition studied

Acute Ischemic Stroke

ICD-10 code

I63.00

ICD-10 code description

Cerebral infarction due to thrombosis of unspecified precerebral artery

Primary outcomes

1

Description

National Institutes of Health Stroke Scale

Timepoint

At entrance , first month and 6th month after intervention

Method of measurement

Neurologic examination of neurologist

2

Description

The Modified Rankin Scale (mRS) for neurologic disability

Timepoint

Neurologic examination of neurologist

Method of measurement

The Modified Rankin Scale (mRS) for neurologic disability

Secondary outcomes

1

Description

Hemorrhagic changes of stroke territory

Timepoint

3th and 7th day after stroke

Method of measurement

CT scan by neurologist

Intervention groups

1

Description

Intervention group: prescribing fingolimod 0.5 miligrams at entrance and after 24 hours

Category

Treatment - Drugs

2

Description

Control group: prescribing placebo at entrance and after 24 hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Hamed Shahriyari

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North Karegar street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hamed Shahriyari

Position

Non consultant specialized physician

Latest degree

Specialist

Other areas of specialty/work

Neurology

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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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

demographic data will be reported as well as the results

When the data will become available and for how long

data will be available in 6 to 9 months after the study
publish

To whom data/document is available

the health care professionals interested in the study
subject will be allowed

Under which criteria data/document could be used

The data will be given providing authentication of the
researcher and all kinds of analysis will be allowed

From where data/document is obtainable

The study attendant Hamed Shahriyari
hamedshahriyari69@gmail.com 0098 912 7962384

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

After introducing and official application by an email, the
study characteristics will be requested and if it is
amenable, the data will be shared by excel or similar
sheets.

Comments