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 befollowed 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 then 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 then 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 analysist 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

City

Tehran

Province

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
Street address
North Karegar street
City
Tehran
Province
Tehran
Postal code
14117 13135
Phone
+98 21 8490 1000
Email
hamedshahriyari69@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
Tehran university of medical sciences, Poursina street
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 8889 6696
Email
tumspr@tums.ac.ir
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
Street address
No18, West 186th street, Bagheri highway, Tehran pars
City
Tehran
Province
Tehran
Postal code
1685883911
Phone
+98 21 7671 0756
Email
hamedshahriyari69@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Hamed Shahriyari

Position
Non consultant specialized physician

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Street address
No18, West 186th street, Bagheri highway, Tehran pars

City
تهران

Province
Tehran

Postal code
1685883911

Phone
+98 21 7671 0756

Email
hamedshahtiyari69@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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HamedShahriyari69@gmail.com

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