Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Dalfampridine on post-stroke motor impairments

Protocol summary

Study aim
To evaluate the effectiveness of dalfampridine in improving motor function in patients with ischemic or hemorrhagic stroke
Design
Randomised blind two groups
Settings and conduct
in the hospital of choice and blinded by student for the examiner
Participants/Inclusion and exclusion criteria
18 to 75 years old. Ability to participate in motor tests (such as walking). Not using drugs similar to dafampridine in the last 3 months
Intervention groups
stroke patients with motor impairment
Main outcome variables
motor assesment scoring

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250526065899N1**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**
Registration date
2026-08-01, 1405/05/10

Registrant information
Name
Abolfazl Basiri
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-08-01, 1405/05/10
Expected recruitment end date
2026-09-21, 1405/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Dalfampridine on post-stroke motor impairments

Public title
The effect of Dalfampridine on post-stroke motor impairments
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18-75 year old stroke patients having the ability to do physical exams No similar medication taken by patients within 3 months
Exclusion criteria:
history of seizure in the past year inability to perform in physical exams
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants who provide written informed consent will be randomly assigned in a 1:1 ratio to either the intervention group (dalfampridine) or the control group (placebo) using simple randomization. The unit of randomization will be the individual participant, and stratified randomization will not be applied in this study. The random allocation sequence will be generated by an independent statistician, who is not involved in participant recruitment, treatment allocation, intervention implementation, or outcome assessment, using computer-generated random numbers. Participants will be assigned to one of the two study groups according to the allocation sequence in the order of their enrollment. To ensure allocation concealment, the randomization sequence will be placed in sequentially numbered, opaque, sealed envelopes (SNOSE). After a participant is definitively enrolled, the corresponding envelope will be opened in numerical order, and the allocation code will be communicated to the hospital pharmacy. Based on this code, the hospital pharmacy will dispense either dalfampridine or an identically appearing placebo with identical labeling. Drug coding and labeling will be performed by the hospital pharmacy or another independent individual not involved in the conduct of the study or outcome assessment. Consequently, participants, investigators, and outcome assessors will remain blinded to treatment allocation until the completion of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind randomized clinical trial. Both the participants and the outcome assessors will be unaware of the assigned interventions. The dalfampridine and placebo will be identical in shape, color, packaging, and method of administration. Drug coding and labeling will be performed by a third party not involved in the intervention or assessment process
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Islamic Azad university tehran medical branch
Street address
No 4, Boustan 5 St, Shahid Afshari St, Heravi Sq, Tehran, Iran
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Province
Tehran
Postal code
1665715696
Approval date
2025-03-21, 1404/01/01
Ethics committee reference number
IR.IAU.TMU.REC.1404.032

Health conditions studied

1

Description of health condition studied
stroke- cva
ICD-10 code
I64
ICD-10 code description
Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description
motor assesment score
Timepoint
4 and 8 weeks after the application
Method of measurement
scale of motor assesment score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the patients who are given the medication dalfampridine 10mg daily for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: the patients of this group would take their other medications of stroke disease but not Dalfampridine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Atiyeh 2 medical facility

Full name of responsible person
Dr Radnoush Pashmforoush

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Web page address
https://tms.iau.ir/research/fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
1

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
Islamic Azad University

Full name of responsible person
Radnoush Pashmforoush

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Neurology

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available