Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effects of caffeine with or without transcranial magnetic stimulation on neurorehabilitation of motor impairments after stroke

Protocol summary

Summary
This study aims to evaluate the effects of caffeine with or without transcranial magnetic stimulation (TMS) in neurorehabilitation after stroke. In this randomized double-blind study (phase 2), 40 patients with stroke, aged 18 to 85 years, from Chamran hospital are randomly allocated to 4 groups: Group A receive TMS with caffeine placebo, group B receive TMS and caffeine, group C receive caffeine and non-stimulating waves of TMS, and group D receive caffeine placebo and non-stimulating waves of TMS. Fugl-Meyer test is used to evaluate motor function and Barthel test is used to determine disability. These patients whose stroke occurred at no more than 1 month are included in the study. Caffeine capsule (200 mg) is used twice a day and TMS is done three times a week for each patient. the primary outcome of this study is the recovery of motor impairments and disability.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2017021832625N1**
Registration date: **2017-04-30, 1396/02/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2017-04-30, 1396/02/10

Registrant information
Name
Mojtaba Keshavarz
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Shiraz University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2017-04-21, 1396/02/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effects of caffeine with or without transcranial magnetic stimulation on neurorehabilitation of motor impairments after stroke

Public title
The effect of caffeine on neurorehabilitation after stroke

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: 1) Age 18 to 85 years 2) Motor impairments after stroke 3) Scores 15 to 55 in Fugl-Mayer test Exclusion Criteria: 1) Severe major depression 2) Severe motor impairment 3) Other neurodegenerative disorders

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
using block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Zand Street
City
Shiraz
Postal code
7194815644
Approval date
2017-02-14, 1395/11/26
Ethics committee reference number
IR.SUMS.REC.1395.182

Health conditions studied

1

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

Primary outcomes

1

Description
Motor impairments
Timepoint
Before treatment and one month after treatment
Method of measurement
Fugl-Meyer test

Secondary outcomes

1

Description
Disability
Timepoint
1 month
Method of measurement
Barthel test

Intervention groups

1

Description
Caffeine, 200 mg capsule, oral, twice a day in 1 month
Category
Treatment - Drugs

2

Description
Flour, 200 mg capsule, oral, twice a day in 1 month
Category
Placebo

3

Description
Transcranial magnetic stimulation, 20 pulses, 10 Hz, 2 seconds, three times a week in 1 month
Category
Other

4

Description
Non-stimulating waves of transcranial magnetic stimulation, 20 pulses, 1 Hz, 2 seconds in 1 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
DR Mojtaba Keshavarz
Street address
Chamran Boulevard
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research of Shiraz University of Medical Sciences
Full name of responsible person
Basir Hashemi
Street address
Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz Neuroscience Research Center
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty