Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation of Neurophysiological and Clinical Effects of Transcranial Magnetic Stimulation of the Motor Cortex Compared to Stimulation of the Cerebellum in Patients with Spastic Stroke

Protocol summary

Study aim

Investigation of Neurophysiological and Clinical Effects of Transcranial Magnetic Stimulation of the Motor Cortex Compared to Stimulation of the Cerebellum in Patients with Spastic Stroke

Design

This is a parallel-group, double-blind randomized clinical trial with 27 patients. Randomization will be performed using block randomization with a block size of 3 to ensure balanced allocation across the groups.

Settings and conduct

This study will be conducted in Medical Centers in Semnan on Stroke Patients. Participants will be randomly assigned to the M1 Group, the Cerebellar Group, or the Control Group. The M1 and Cerebellar Groups will receive 10 sessions of ITBS, and the Control Group will receive 10 sham sessions. The study is double-blind; Participants and Outcome Assessors are blinded to group allocation.

Participants/Inclusion and exclusion criteria

Participants Are Patients With Unilateral Stroke Aged 40 To 75 Years With Wrist Flexor Spasticity And Adequate Cognitive Ability, At Least 6 Months Post-Stroke, And No Botulinum Toxin Injection In The Past 6 Months. Individuals With Cerebellar Or Brainstem Lesions, Severe Psychiatric Or Communication Disorders, Progressive Neurological Diseases, Active Medical Conditions, Or Contraindications To ITBS Are Excluded.

Intervention groups

Participants In The M1 Group (Group A) Will Receive 10 Sessions Of ITBS Over The Primary Motor Cortex Of The Affected Hemisphere. The Cerebellar Group (Group B) Will Receive 10 Sessions Of ITBS Over The Cerebellum Of The Affected Hemisphere. The Control Group (Group C) Will Receive 10 Sham Sessions Identical To The Intervention Groups, With The Device Turned Off To Control For Placebo Effects.

Main outcome variables

Motor Cortex Excitability (RMT, MEP, ESP); Wrist Flexor Muscle Spasticity (MMAS, RMS)

General information

Reason for update

Acronym

iTBS

IRCT registration information

IRCT registration number: **IRCT20260212068838N1**
Registration date: **2026-03-22, 1405/01/02**
Registration timing: **prospective**

Last update: **2026-03-22, 1405/01/02**
Update count: **0**

Registration date

2026-03-22, 1405/01/02

Registrant information

Name

Mona Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-04, 1405/01/15

Expected recruitment end date

2027-01-05, 1405/10/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of Neurophysiological and Clinical Effects of Transcranial Magnetic Stimulation of the Motor Cortex Compared to Stimulation of the Cerebellum in Patients with Spastic Stroke

Public title
Comparison of the Effects of Primary Motor Cortex Magnetic Stimulation and Cerebellar Stimulation on Reducing Muscle Spasticity in Stroke Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Stroke Aged 40 to 75 Years At Least 6 Months And No More Than 2 Years Have Passed Since The Onset Of Stroke Unilateral Ischemic Or Hemorrhagic Stroke Confirmed By CT Scan Or MRI Presence Of Spasticity In The Wrist Flexor Muscles With A Score Greater Than 1 On The Modified Modified Ashworth Scale (MMAS) No History Of Botulinum Toxin Injection Within The Past 6 Months Adequate Cognitive Ability To Complete The Assessment Procedures And Treatment Protocol
Exclusion criteria:
Patients With Cerebellar Or Brainstem Lesions Presence Of Severe Psychiatric Or Communication Disorders That Interfere With Cooperation In The Study Process Progressive Neurological Diseases Such As Neurodegenerative Disorders And Active Medical Conditions Including Infections Presence Of Concomitant Neurological Diseases Or Orthopedic Disorders Affecting Upper Limb Function Individuals With Contraindications To Intermittent Theta Burst Stimulation (iTBS) Such As History Of Seizure, Cerebral Aneurysm, Intracranial Metal Implants, Cardiac Pacemaker, Or Pregnancy Inability To Understand Or Comply With The Study Procedures
Age
From **40 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **27**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization With A Block Size Of 3 (Equal To The Number Of Study Groups) Will Be Used To Ensure Balanced Allocation Of Participants Across All Groups Throughout The Recruitment Process. For Each Three-Participant Block, Six Possible Allocation Sequences Exist: T1T2C, T1CT2, T2T1C, T2CT1, CT1T2, CT2T1 Using Microsoft Excel Software, Nine Random Blocks Will Be Generated, Providing A Total Of 27 Allocation Slots For Participant Assignment. The Allocation Sequence For Each Block Will Be Placed In Opaque Sealed Envelopes And Opened Sequentially According To The Order Of Participant Enrollment To Maintain Allocation Concealment.
Blinding (investigator's opinion)
Double blinded
Blinding description
he researcher will be blind to the intervention using the research assistant and he/she is absent in the treatment room. The outcome evaluator will vary with the researcher and research data be given him with code and is unaware of the participants intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی سمنان
Street address
Headquarters of Semnan University of Medical Sciences, Basij Blvd., Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2026-01-19, 1404/10/29
Ethics committee reference number
IR.SEMUMS.REC.1404.304

Health conditions studied

1

Description of health condition studied
Spastic Stroke
ICD-10 code
G80.2
ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Motor Cortex Excitability Of The Affected Hemisphere Based On Resting Motor Threshold (RMT) Of The Extensor Carpi Radialis Brevis Muscle
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Transcranial Magnetic Stimulation Device

2

Description
Amplitude of Motor Evoked Potential (MEP) Responses of the Extensor Carpi Radialis Brevis Muscle in the Affected Hemisphere
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Surface Electromyography

3

Description
Evoked Silent Period (ESP) of the Extensor Carpi Radialis Brevis Muscle in the Affected Hemisphere
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Transcranial Magnetic Stimulation Device

4

Description
Wrist Flexor Muscle Spasticity
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Modified Modified Ashworth Scale

5

Description
Wrist flexor and extensor muscle activity recorded as Root Mean Square (RMS) of the sEMG signal in active and passive movements
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Surface Electromyography

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Stroke-specific Quality of Life Questionnere

2

Description
Upper Limb Function
Timepoint
Before The Intervention, 10 Days After The Start Of The Intervention, And One Month After The End Of The Intervention
Method of measurement
Fugl-Meyer Assessment

Intervention groups

1

Description
Intervention group: The group receiving transcranial magnetic stimulation of the motor area of the brain (M1-iTBS). To stimulate the M1, iTBS will apply over the motor hotspot of the affected extensor carpi radialis brevis muscle. The stimulation intensity is 80% of the resting motor threshold. The iTBS protocol consists of 10 bursts, each of which is compose of three stimuli at 50 Hz, repeated at a theta frequency of 5 Hz every 10 s for a total of 600 stimuli (200 s). Each patient received 10 session of treatment.
Category
Treatment - Devices

2

Description
Intervention group: The group receiving transcranial magnetic stimulation of the cerebellum (Cerebellum-iTBS). In this group, iTBS will apply over the contralesional cerebellum. The stimulation intensity is 80% of the resting motor threshold. The iTBS protocol consists of 10 bursts, each of which is compose of three stimuli at 50 Hz, repeated at a theta frequency of 5 Hz every 10 s for a total of 600 stimuli (200 s). Each patient received 10 session of treatment.
Category
Treatment - Devices

3

Description
Control group: Group receiving sham transcranial magnetic stimulation (sham-iTBS). In the sham iTBS

group, iTBS was randomly applied over the M1 or cerebellum. Stimulation in the sham rTMS group is turn off, while the coils remained in place and a noise similar to the sound of real iTBS was heard in the space.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Semnan unuversity of medical science, Neuromuscular Rehabilitation Research Center

Full name of responsible person
Mona Ramezani

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Neuromuscular Rehabilitation ResearCenter, Tabatabaee Clinic, Qods Blvd., Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Ali Rashidi Pour

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Mona Ramezani

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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Neuromuscular Rehabilitation Research Center, Tabatabaee Clinic, Qods Blvd., Semnan

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Person responsible for scientific inquiries

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Associate professor

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

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