Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of repetitive extracerebral magnetic stimulation (rTMS) in improving motor performanceand swallowing disorders in patients with ischemic stroke

Protocol summary

Study aim
To determine the effect of repetitive transcranial magnetic stimulation (rTMS) on motor and swallowing improvement in ischemic stroke patients

Design
Semi-experimental before–after study with one group (n=205). No randomization. Non-drug phase.

Settings and conduct
A semi-experimental before–after study conducted at the Rehabilitation Clinic of Jam Hospital. Eligible ischemic stroke patients will be enrolled after informed consent and receive rTMS sessions per standard protocol. Motor and swallowing functions are assessed before and after treatment. No blinding applied.

Participants/Inclusion and exclusion criteria
Inclusion: Confirmed ischemic stroke (CT/MRI), age 25–65, motor or swallowing deficit, ≥2 weeks post-stroke, stable, informed consent. Exclusion: Hemorrhagic stroke, active epilepsy, metal implants, severe cognitive/psychiatric disorder, pregnancy, non-cooperation.

Intervention groups
All eligible ischemic stroke patients receive rTMS per protocol. Motor and swallowing functions are assessed by Fugl-Meyer and FOIS before and after treatment. No control group.

Main outcome variables
Change in Fugl-Meyer Motor Score; Change in Functional Oral Intake Scale before and after intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251027067782N1**
Registration date: **2025-11-27, 1404/09/06**
Registration timing: **prospective**

Last update: **2025-11-27, 1404/09/06**
Update count: **0**

Registration date
2025-11-27, 1404/09/06

Registrant information

Name
Amirali Akbari baghbaderani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-07, 1404/09/16

Expected recruitment end date
2026-07-22, 1405/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of repetitive extracerebral magnetic stimulation (rTMS) in improving motor performanceand swallowing disorders in patients with ischemic stroke

Public title

The effect of repetitive magnetic stimulation on movement and swallowing in patients with ischemic stroke

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed ischemic stroke by CT or MRI Presence of motor or swallowing dysfunction after stroke At least two weeks post-stroke (clinically stable phase) Ability to attend therapy sessions Written informed consent obtained

Exclusion criteria:

Hemorrhagic stroke History of epilepsy or active seizures Metallic implants or contraindicated medical devices for rTMS Severe psychiatric or cognitive disorders Inability to cooperate in therapy sessions

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **205**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This study is a semi-experimental (before–after) design in which ischemic stroke patients are evaluated before and after receiving repetitive transcranial magnetic stimulation (rTMS) in terms of motor and swallowing function. Due to the therapeutic nature of the intervention and ethical and practical limitations in establishing a control group, a before–after design was chosen so that each patient serves as their own control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Biomedical Ethics Committee of Islamic Azad University, Tehran Medical Sciences Branch

Street address

Tehran, Shahid Ghandi St., North of Sadr Bridge, Shariati St., Islamic Azad University, Tehran Medical Sciences Branch

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Province

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Postal code

1919893651

Approval date

2024-12-24, 1403/10/04

Ethics committee reference number

IR.IAU.TMU.REC.1403.356

Health conditions studied

1

Description of health condition studied

Ischemic Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Change in motor function score measured by the Fugl Meyer Assessment from before the intervention to after completion of the intervention

Timepoint

Measurement of motor function at baseline before the start of the intervention and after completion of the full course of repetitive transcranial magnetic stimulation sessions

Method of measurement

Motor function measurement using the Fugl Meyer Assessment administered by a trained rehabilitation specialist

2

Description

Change in swallowing function score measured by the Functional Oral Intake Scale from before the intervention to after completion of the intervention

Timepoint

Measurement of swallowing function at baseline before the start of the intervention and after completion of the full course of repetitive transcranial magnetic stimulation sessions

Method of measurement

Swallowing function measurement using the Functional Oral Intake Scale administered by a trained speech therapist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with ischemic stroke receive repetitive transcranial magnetic stimulation according to the standard protocol. The intervention consists of stimulation of the primary motor cortex of the affected hemisphere at a frequency of ten hertz, an intensity equal to one hundred percent of the motor threshold, a total of one thousand five hundred pulses per session, and an approximate duration of twenty minutes. Treatment sessions are delivered five times per week for two consecutive weeks. No additional intervention is applied during the treatment period.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Jam Hospital Rehabilitation Clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Golaleh Shahabpour
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No. 197, Yakhchal Street, Shariati Street, Near Sadr Bridge, Tehran, Iran
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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
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Amirali Akbari baghbaderani
Position
Medical intern
Latest degree
A Level or less
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the sensitive nature of individual patient data in ischemic stroke populations and the substantial risk of re-identification even after de-identification procedures, the ethics committee has imposed specific restrictions on data sharing. To ensure maximum confidentiality and full compliance with ethical and legal requirements, the individual participant data from this study cannot be publicly shared at this time. No additional information is available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available