

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

Registration timing: **prospective**

Study aim

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

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

Update count: **0**

Registration date

2025-11-27, 1404/09/06

Design

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

Registrant information

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Amirali Akbari baghbaderani

Name of organization / entity

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Iran (Islamic Republic of)

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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.

Recruitment status

Recruitment complete

Funding source

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.

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

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.

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251027067782N1**

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

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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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

Amirali Akbari Baghbaderani

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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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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

Other areas of specialty/work

General Practitioner

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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

Person responsible for updating data**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

Other areas of specialty/work

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