

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effects of high-frequency repetitive transcranial magnetic stimulation combined with Physiotherapy in Rehabilitation of Functional outcomes, Balance, Quality of life and depression in stroke patients: A randomized controlled trial.

Protocol summary

Study aim

Comparison of effects of treatment with HF-rTMS(High-Frequency Repetitive Transcranial Magnetic Stimulation) and rehabilitation, with rehabilitation alone, on balance, functional independence, quality of life and depression of patients after stroke

Design

Two arms parallel-group randomized trial on 36 patients with blinded outcome assessment

Settings and conduct

Stroke patients are visited in the specialty clinic of Emam Reza hospital of Tabriz by an experienced neurologist and then referred for initial assessments. Patients undergo interventions based on their group in Physigo Rehabilitation center, and assessment is done immediately after, and 1 month after interventions. Neurologist, researcher, outcome evaluators and the statistician are blinded.

Participants/Inclusion and exclusion criteria

Adult patients with proven ischaemic or hemorrhagic stroke, suffering from movement disorders of lower limbs; without a past history of epilepsy or other contraindications of rTMS

Intervention groups

Subjects that conform to inclusion criteria are allocated to these two groups: 1- Intervention: Real HF-rTMS and conventional rehabilitation 2- Control: Sham HF-rTMS and conventional rehabilitation

Main outcome variables

Berg Balance Scale(BBS) score; Berg Depression Short Inventory (BDI-S) score; Adults' Activities of Daily Living (ADL) Questionnaire score; WHO Short-form Quality of Life Questionnaire (WHOQOL-BREF) score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100720004422N8**

Registration date: **2020-09-01, 1399/06/11**

Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**

Update count: **0**

Registration date

2020-09-01, 1399/06/11

Registrant information

Name

Seyed Kazem Shakouri

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of high-frequency repetitive transcranial magnetic stimulation combined with Physiotherapy in Rehabilitation of Functional outcomes, Balance, Quality of life and depression in stroke patients: A randomized controlled trial.

Public title

Effects of rTMS in rehabilitation after stroke

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Proven CVA via MRI At least 3 months after stroke Stroke in MCA artery Motor disorder in lower limbs due to recent stroke Mild to moderate disorder of balance measured by Berg balance scale

Exclusion criteria:

Flaccid paraplegia Presence of a cardiac pacemaker, cochlear implant or any metal implant in patient's skull Previous treatment sessions with rTMS History of severe psychiatric disorders, including suicidal thoughts Pregnancy History of epilepsy History of other Neurologic disorders of balance Consumption of drugs with a potential disruptive effect on patient's balance Recent brain or spinal cord surgery Recent brain or spinal cord surgery Severe musculoskeletal disorders of lower limbs

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

A block randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS) with block sizes of 2 and 4. Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

Blinding (investigator's opinion)

Double blinded

Blinding description

An independent researcher will randomise eligible participants. The researcher administering rTMS will be unblinded. To ensure allocation concealment, the independent researcher (randomiser) will provide allocation details (stimulation type) via a participant ID-

coded email to the rTMS administrator immediately before the rTMS session. Participants will be remained blind to stimulation type until the end of procedures, as the researcher conducting assessments.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences central offices building No.2, Golgasht St, Tabriz

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Tabriz

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East Azarbaijan

Postal code

5166969396

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.TBZMED.REC.1399.069

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes**1****Description**

Berg Balance Scale Score

Timepoint

Before Intervention, After Intervention, After 1 month

Method of measurement

Berg Balance Scale Score

2**Description**

Berg Depression Short Inventory (BDI-S) score

Timepoint

Before Intervention, After Intervention, After 1 month

Method of measurement

Berg Depression Short Inventory (BDI-S) score

3

Description

Adults activities of daily living Questionnaire

Timepoint

Before Intervention, After Intervention, After 1 month

Method of measurement

Adults activities of daily living Questionnaire Score

4

Description

WHO Short-form Quality of Life Questionnaire (WHOQOL-BREF) score

Timepoint

Before Intervention, After Intervention, After 1 month

Method of measurement

WHO Short-form Quality of Life Questionnaire (WHOQOL-BREF) score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 sessions of HF-rTMS, delivered to lesional primary motor cortex area (M1), Frequency is set to 10 HZ. Dose for every session is 1000 pulses delivered in 10 trains of 10 seconds, with 50 seconds of rest in between. The total time for every session is 10 minutes. Patients undergo conventional rehab for stroke such as ROM and strengthening exercises, sitting and standing training, gait training with mirror and electrical stimulation based on the severity of symptoms.

Category

Rehabilitation

2

Description

Control group: Sham rTMS sessions are performed with a protocol similar to the intervention group, although the orientation of the coil is different and the intensity is set to minimum and simulated sounds are played through a speaker. The rehabilitation protocol is the same as the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Medicine & Rehabilitation Clinic of Emam Reza Hospital

Full name of responsible person

Seyyed Kazem Shakouri

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Physical medicine and rehabilitation ward, Emam Reza Hospital, Golgasht st, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ata Mahmoudpour

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Kiarash Kordshakeri

Position

Medical Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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