Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Country

Iran (Islamic Republic of)

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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
City
Tabriz
Province
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 o 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
Street address
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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Attar Neyshaburi St., Tabriz University of Medical Sciences, Tabriz
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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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Physical medicine and rehabilitation ward, Emam Reza Hospital, Golgasht st, Tabriz

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Person responsible for updating data

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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