Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of repetitive trans-cranial magnetic stimulation (rTMS) of lower limb motor cortex on Lower extremity spasticity in patients with hereditary spastic paraplegia (HSP): A randomized sham-controlled double-blind study

Protocol summary

Study aim

1. Effectiveness of rTMS on improvement of lower limb spasticity 2. Effectiveness of rTMS on improvement of modified Ashworth scale (MAS) of knee 3. Effectiveness of rTMS on improvement of 10-meter walking test 4. Effectiveness of rTMS on improvement of Fugl-Meyer lower limb functional assessment (FMA-LE) 5. Effectiveness of rTMS on improvement of quality of life based on SF-36

Design

Double blind, randomized, Sham-controlled trial

Settings and conduct

Place of study: Neurology department of Shariati hospital Patients with familial or sporadic hereditary spastic paraplegia who are classified as definitely affected or probably affected based on Fink's criteria will be registered between 2016-18. designated sample size for the study is 10 patients, 5 in each group. patients would be randomized to either receive active 5 Hz rTMS or sham rTMS. Patients will be evaluated for following outcomes at baseline, upon completion of the intervention and 1 month after intervention: Average score of modified Ashworth scale in both knees Gait based on 10-meter walking test Lower limb motor function based on Fugl-Meyer lower extremity functional assessment (FMA-LE) Quality of life based on short form survey 36 (SF-36)

Participants/Inclusion and exclusion criteria

Inclusion: Patients with minimum age of 18 who are classified as definitely affected or probably affected based on Fink's criteria. Exclusion: History of seizure, uncontrolled hypertension, History of head trauma during 1 month prior to study, artificial heart valve or pacemaker, metallic body in head

Intervention groups

Active group: 5-Hz rTMS) 5 sessions on 5 consecutive days. Sham group: Sham rTMS, similar sessions and duration to active group but with coil placed perpendicular, hence, no stimulation.

Main outcome variables

Effect of high frequency rTMS on lower limb spasticity of HSP patients based on average modified Ashworth scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170703034879N2**
Registration date: **2020-09-15, 1399/06/25**
Registration timing: **retrospective**

Last update: **2020-09-15, 1399/06/25**
Update count: **0**

Registration date

2020-09-15, 1399/06/25

Registrant information

Name

Siamak Abdi

Name of organization / entity

Neurology department- shariati hospital- Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2017-06-22, 1396/04/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
2017-06-22, 1396/04/01
Actual recruitment end date
2019-06-22, 1398/04/01
Trial completion date
2019-07-23, 1398/05/01

Scientific title
Effect of repetitive trans-cranial magnetic stimulation (rTMS) of lower limb motor cortex on Lower extremity spasticity in patients with hereditary spastic paraplegia (HSP): A randomized sham-controlled double-blind study

Public title
Effect of rTMS on HSP
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis based on Fink's Criteria Signed written informed consent
Exclusion criteria:
History of Seizure Uncontrolled hypertension Cochlear implant Cardiac Pacemaker Foreign body in patient's body
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **10**
Actual sample size reached: **8**
Randomization (investigator's opinion)
Randomized
Randomization description
We used computer-generated blocks for randomization. We asked a third party with no role in patient registration or data analysis to generate a number of blocks with 4 spots, 2 for intervention and 2 for sham. When the patient registration started, the person in charge of randomization was asked to start choosing a random block and inform the operator (who was an independent person with no role in patient registration and analysis) of the type of intervention for each patient in order of registration. in total 2 blocks of 4 were used for our 8 patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
For patient's in sham group, we used the same coil in active group but we placed it perpendicular to patient's scalp, therefore we were able to reproduce the somatic vibration sensation and acoustic artifact without stimulating motor cortex. As patients would receive intervention in separate appointments and there was no contact between patients, apart from the operator of rTMS, everyone -including the clinician who evaluated the outcomes and the analyst- was blind to the intervention for each patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
School of Medicine - Poursina street
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2016-11-22, 1395/09/02
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1089

Health conditions studied

1

Description of health condition studied
Hereditary spastic paraplegia
ICD-10 code
G11.4
ICD-10 code description
Hereditary spastic paraplegia

Primary outcomes

1

Description
Improvement of lower limb spasticity based on modified Ashworth scale
Timepoint
Before intervention, upon completion of 5 sessions of

rTMS, 1 moth after intervention

Method of measurement

Modified Ashworth Scale (MAS)

Secondary outcomes

1

Description

Change in patients' mobility based on 10-meter walking test

Timepoint

Before intervention, upon completion of 5 sessions of rTMS, 1 month after intervention

Method of measurement

10-meter Walking test

2

Description

Change in motor function of lower limb

Timepoint

Before intervention, upon completion of 5 sessions of rTMS, 1 month after intervention

Method of measurement

Fugl-Meyer Assessment of lower limb (FMA-LE)

3

Description

Quality of Life

Timepoint

Before intervention, upon completion of 5 sessions of rTMS, 1 month after intervention

Method of measurement

Short form survey 36 (SF-36)

Intervention groups

1

Description

Intervention group: 5 sessions of 5 Hz rTMS on 5 consecutive days. each session comprised of 5 trains of 60 second duration and 2 minute inter train interval.

Category

Rehabilitation

2

Description

Control group: 5 sessions of sham rTMS with same duration as active intervention group with coil placed perpendicular to patient's scalp.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Mohsen Kordjazi

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EMG-NCV department, Shariati hospital, Jalal-e-Al-e-Ahmad Hwy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr Siamak Abdi

Position
Assistant professor of neurology

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Mentioned information will be made available along with the manuscript as supplementary files.

When the data will become available and for how long
Same time as the publication of the manuscript

To whom data/document is available
All those who have access to the published manuscript.

Under which criteria data/document could be used
Those who wish to perform further analysis on the data must submit their written request to the corresponding author of the article.

From where data/document is obtainable

Corresponding author of the published manuscript.

What processes are involved for a request to access data/document

any request received by corresponding author will be shared with the research team and decision upon the requested permission will be made available to the applicant.

Comments