# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 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

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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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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mohammad Ali Sahraian

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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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## Person responsible for updating data

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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**