

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Therapeutic effects of repetitive transcranial magnetic stimulation therapy on central nervous system structure and function, neuromuscular properties and gait in children with cerebral palsy

Protocol summary

Summary

Objectives: We will study therapeutic effects of repetitive transcranial magnetic stimulation (rTMS) therapy on central nervous system structure and function, neuromuscular properties and gait in children with cerebral palsy. Design: a randomized double blind controlled study Setting and Conduct: A hundred children with cerebral palsy will be referred to neural engineering and rehabilitation center of Noorafshar hospital from rehabilitation and medical centers. Subjects, who are diagnosed by pediatric neurologists, will be randomly allocated to study and control groups. Major Inclusion and Exclusion criteria: Four to fourteen years old hemiplegic patients with spasticity in lower extremities who do not have metal implants or pacemaker and also have the ability of following commands will participate in this study. Intervention: The study group will receive rTMS with air film coil and the control group will receive rTMS with sham coil. Each group will receive 25 minutes of 1 Hz repetitive transcranial magnetic stimulation for 3 days per week for 2 months. Main outcome measures (variables): In addition to evaluating the clinical changes, brain structural changes, activity level of the descending neural pathways including corticospinal tracts, neuromuscular properties, balance, and the lower limbs movement ability of the children will be quantified.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092525568N2**

Registration date: **2016-11-10, 1395/08/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-10, 1395/08/20

Registrant information

Name

Seyed Mohammad Mehdi Mirbagheri

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

mehdi@northwestern.edu

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of repetitive transcranial magnetic stimulation therapy on central nervous system structure and function, neuromuscular properties and gait in children with cerebral palsy

Public title

Improvement of motor function and neuromuscular disorders by repetitive transcranial magnetic stimulation

therapy in children with cerebral palsy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: hemiplegic patients diagnosed by a pediatric neurologist; spasticity in lower extremities (Modified Ashworth Scale score more than 1); ability to attend training or test sessions; ability of following commands
Exclusion criteria: having severe mental retardation; epilepsy; chromosomal anomaly; or genetic syndrome; severe brain structural anomaly; pacemaker or any other metallic implants; not attending treatment sessions regularly

Age
From **4 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
coin-flip

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
PoorSina St., Ghods St., Enghelab St., Tehran

City
Tehran

Postal code
1417613151

Approval date
2016-01-13, 1394/10/23

Ethics committee reference number
IR.TUMS.REC.1394.1649

Health conditions studied

1

Description of health condition studied
spastic hemiplegic cerebral palsy

ICD-10 code
G80.2

ICD-10 code description
Spastic hemiplegic cerebral palsy

Primary outcomes

1

Description
Mean Diffusivity

Timepoint
before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement
Magnetic Resonance Imaging Acquisition; Post Analysis

2

Description
Berg Balance Scale

Timepoint
before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement
Clinical evaluations

3

Description
Center of Pressure Distance

Timepoint
before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement
Gait Analysis

4

Description
Stride Velocity

Timepoint
before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement
Gait Analysis

5

Description
Maximum Voluntary Contraction

Timepoint
before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Isokinetic

6**Description**

Fractional Anisotropy

Timepoint

before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Magnetic Resonance Imaging Acquisition; Post Analysis

7**Description**

Transcranial Magnetic Stimulation Motor threshold

Timepoint

before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Transcranial Magnetic Stimulation Device;
Electromyography Device

8**Description**

Hoffman Reflex

Timepoint

before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Electromyography Device

9**Description**

Muscle Weakness

Timepoint

before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Electromyography Device

10**Description**

Tissue Elasticity

Timepoint

before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Sonoelastography

11**Description**

Velocity and Endurance

Timepoint

before intervention; one month after the beginning of intervention; at the end of intervention; one month after the end of intervention

Method of measurement

Clinical evaluations

Secondary outcomes**1****Description**

-

Timepoint

-

Method of measurement

-

Intervention groups**1****Description**

Intervention group: will receive 25 minutes of 1 Hz repetitive transcranial magnetic stimulation (1500 pulses) with air film coil for 3 days per week for 8 weeks. The stimulation may be paused based on subject's tolerance.

Category

Treatment - Devices

2**Description**

Control group: will receive 25 minutes of 1 Hz repetitive transcranial magnetic stimulation (1500 pulses) with sham coil for 3 days per week for 8 weeks.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Noorafshar hospital

Full name of responsible person

Maryam Shahrokhnia

Street address

Sadeghin St., Khodaverdi St., PoorEbtahaj St.,
Niavaran Sq., Tehran

City

Tehran

2**Recruitment center****Name of recruitment center**

Children's Medical Center

Full name of responsible person

Parmida Moradi Birgani

Street address

No 62, beside Emam Khomeini hospital, Qarib St,
Keshavarz Blvd, Tehran

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Fax**Email**

parmida.mb@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Tehran University of
Medical Sciences

Full name of responsible person

Seyed Mohamad Mehdi Mirbagheri

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Tehran University of Medical Sciences, Pour Sina St.,
Ghods St., Enqelab Sq. Tehran

City

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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

Vice chancellor for research of Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Parmida Moradi Birgani

Position

Doctor of Philosophy (PhD) student

Other areas of specialty/work**Street address**

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Full name of responsible person

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Tehran University of Medical Sciences

Full name of responsible person

Shokoofeh Parvin

Position

Master of Science student

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty