

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

+98 21 6405 3252

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

City

Tehran

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

Street address

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

City

Tehran

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**

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

City

Tehran

Postal code

1417613151

Phone

+98 21 6646 6383

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Mohamad Mehdi Mirbagheri

Position

Post Doctoral

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

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

City

Tehran

Postal code

1417613151

Phone

+98 21 6646 6383

Fax**Email**

mehdi@northwestern.edu

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shokoofeh Parvin

Position

Master of Science student

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

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

City

Tehran

Postal code

1417613151

Phone

+98 21 6646 6383

Fax**Email**

sh-parvin@razi.tums.ac.ir

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