Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of repetitive transcranial magnetic stimulation on dysarthria and postural disturbance in patients with progressive supranuclear palsy

Protocol summary

Study aim

we aim to measure the effect of rTMS on dysarthria and postural disturbance in patients with PSP in Mashhad on 2023

Design

clinical trial with intervention and sham groups,parallel,triple blind ,randomized,in phase 2-3 design on 12 PSP patients,enrolled in may and jun 2023 and followed for 4 months

Settings and conduct

12 PSP patients were first scored for movement (by motion kinematics analysis) and speech and swallowing (scoring by speech therapist) from patients diagnosed with PSP who were chosen from the movement disorders clinic . The place of rTMS is the psychiatry clinic, the speech and swallowing evaluation place will be the speech therapy clinic ,the balance analysis place will be in the physiotherapy clinic. The patients are then randomly and blindly divided into intervention and sham groups and receive 10 sessions of rTMS every other day (in the sham group, a three cm nonconductor piece is placed between the cap of the device and the scalp) blinding of the patients and the researchers is done by sealed letters that contain codes determined based on permutation blocks.

Participants/Inclusion and exclusion criteria

the patients who have PSP diagnosis that have ability for walking a few steps and speaking in a few words but they don't have previous dysarthria ,properioception or vesttibular sensory disorders and stroke and also who don't have rTms containdications

Intervention groups

rTms is done by two magsim 200 that is connectedto 2 groups of flat coils and the intensity of produced MEP is until 1mV. the coil sites in contact with skullis 2 cm in laterals and 1 cm below the inion.

Main outcome variables

postural disturbance with motion analysis and kinematic analysis of movement and scoring based on the calculation of the result of the measured forces;state of dysarthria and swallowing with the Pietrenberg auditory-perceptual evaluation index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230504058069N1**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **retrospective**

Last update: **2023-06-27, 1402/04/06**
Update count: **1**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name
Mina FarahNejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 912 763 5742

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m.farahnezhad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-26, 1402/03/05

Expected recruitment end date

2023-06-05, 1402/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of repetitive transcranial magnetic stimulation on dysarthria and postural disturbance in patients with progressive supranuclear palsy

Public title

RTMS effects on PSP patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

PSP patients that was diagnosed by national institute of neurologic disease and stroke for PSP citeria patient who can stand alon and without helping patient who can walking at least a few steps without helping patient who can speak and answer the questions patient who has signed the informed consent form to enter the plan

Exclusion criteria:

patient who was diagnosed dementia by DSM-IV criteria patient who had vestibular or properioception or sensory deficits patient who has any contraindication of brain stimulation (such as pacemakers or presence of metal objects in the head) the patient had dysartheria before the onset of disease patient who had past medical history of stroke patient who is mute

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

there was used randominaztion techniques by blocks for patients' groups randominazation, for this purpose we must make a block by 30 charachters with combination of A ,B alphabet in "sealed envelope" site and use it for randominazation. we use allocation concealment by sealed envelops

Blinding (investigator's opinion)

Double blinded

Blinding description

blinding was done in participant patients,investigators and outcome assesors.patients and investigators by using a secret code in the selead envelopes remain blinded and information analizer is chosen from out of researcher group Intervention patient (receive RTMS or sham) in sealed envelopes that code are received. Coding by one of the project collaborators It takes place and the doctor, evaluator and patient are blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committees of school of medicine-Mashhad university of medical sciences

Street address

Research and Technology Vice-Chancellor, Qurashi Building, next to Hoize Cinema,University St.,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

1496960720

Approval date

2022-11-08, 1401/08/17

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.663

Health conditions studied

1

Description of health condition studied

PSP Proressive supranuclear palsy

ICD-10 code

G23.1

ICD-10 code description

Progressive supranuclear ophthalmoplegia [Steele-Richardson-Olszewski]

Primary outcomes

1

Description

Checking the postural instabilility of patients

Timepoint

The beginning of the study (before starting rTMS), the end of receiving rTMS, four months later

Method of measurement

Kinematic analysis of scoring movement based on the results of forces and energy

2

Description

Checking the speech and swalling of patients

Timepoint
The beginning of the study (before starting rTMS), the end of receiving rTMS, four months later
Method of measurement
Wanberg's auditory-perceptual assessment index and the Northwestern swallowing disorder test

Secondary outcomes

1

Description
کیفیت زندگی بیماران
Timepoint
The beginning of the study and the end of the study
Method of measurement
PDQL questionnaire

Intervention groups

1

Description
Intervention group: 6 PSP patients who receive 10 sessions of rTMS with 900 daily pulses of 10 Hz every other day. The location of the coils will be in contact with the skull two centimeters on the sides and one centimeter below the inion
Category
Rehabilitation

2

Description
Control group: 6 PSP patients who receive 10 sessions of rTMS every other day ,along with a 3 cm non-conductive object between the scalp and the cap of the device and 900 daily pulses of 10 Hz. The location of the coils will be in contact with the skull two centimeters on the sides and one centimeter below the inion.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of movement disorders, the office of the first executive of the study
Full name of responsible person
Mina FarahNezhad
Street address
unit 303, third floor, east wing, G4 tower,g towers, before Kharazi highway,, Northern Research Blvd.,Chitgar,Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
dr. Ghayoor-e-mobarhan
Street address
Research and Technology Vice-Chancellor, Qorshi Building, next to Hoizeh Cinema, University Street,Mashhad
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mina FarahNezhad
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Unit 303,Eastern Wing, Third Floor,Tower G, Tower G4,before Kharazi Highway,Northern Pazhouhesh Blvd,Chitgar,Tehran

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

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All the potential data of movement score and questionnaires and speech and swallowing scores of patients can be shared after making them non-identifiable

When the data will become available and for how long
Access starts 6 months to a year after publication

To whom data/document is available
only available for people working in academic institutions

Under which criteria data/document could be used
It is possible to use the documents of this research only by mentioning the names of its researchers in articles and academic researches.

From where data/document is obtainable
from responsible author: Mina Farah Nejad Email: m.farahnezhad@yahoo.com and farahnezhadm991@mums.ac.ir Phone number: 00989127635742

What processes are involved for a request to access data/document
After requesting to receive the research documents by the researcher's academic email and after explaining about the research and the reason for the need of the desired documents by sending to the responsible author's email, if accepted, it will be sent within 1 month at the latest

Comments