Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Effect of Repetitive Transcranial Magnetic Stimulation over the supplementary motor area and dorsolateral prefrontal cortex in improvement of gait in Parkinson’s disease

Protocol summary

Study aim
Conducting research to replace drug therapy with a safe intervention (rTMS) to improve walking and movement problems in patients with Parkinson's disease.

Design
A clinical trial with a control group - double-blind - randomized - on 21 patients - rand function of Excel software was used for randomization

Settings and conduct
The place of study is in the research center clinic of Semnan University of Medical Sciences The method of doing the work is that the patients are divided into 3 groups (2 intervention groups and 1 control group), in one intervention group, rTMS intervention is applied on the SMA cortices and in the other group on the DLPFC area, and in the control group, a silent device is applied on the heads of patients with Parkinson's to get visual and sensory feedback. and the evaluation is done by the three dimensional motion analysis device before and after the intervention and in the 1-month follow-up and the results are analyzed The study is double-blind, so that patients and clinical caregivers are blinded

Participants/Inclusion and exclusion criteria
People with Parkinson's who know the ability to walk independently are included in this study, and people with a history of cerebral hemorrhage or cerebral plaque and a history of epilepsy should not be included in the study.

Intervention groups
The rTMS device intervention is in 2 treatment groups, and in the control group, we turn off the device and place it on the patient's head so that the patient receives visual and sensory feedback for the treatment.

Main outcome variables
Examining walking parameters such as joint angles in the hip, knee and ankle joints and the force exerted by the foot when putting weight on each foot

General information

Reason for update

Acronym
EROSDIGPD

IRCT registration information
IRCT registration number: **IRCT20230125057225N1**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **prospective**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**

Registration date
2023-02-01, 1401/11/12

Registrant information

Name
Ali Heidarinejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4494 4265

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-09, 1401/11/20

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of Repetitive Transcranial Magnetic Stimulation over the supplementary motor area and dorsolateral prefrontal cortex in improvement of gait in Parkinson’s disease

Public title
Effect of rTMS device in improving walking in patients with Parkinson's disease

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with advanced Parkinson's (patients who are in advanced stages often have movement problems - incontinence - insomnia and dementia) People with Parkinson's disease have freezing of gait (FOG). People with Parkinson's who take L-Dopa People who are over 45 years old (according to the opinion of the neurologist who advised the article) The patient should be able to walk without crutches

Exclusion criteria:
Associated painful conditions that may distort the clinical picture of the study People who have a history of epilepsy and have a history of taking antiepileptic drugs such as benzodiazepines. People with a history of cerebral hemorrhage People who have problems such as brain aneurysm or brain plaque People with dementia Based on the Bech questionnaire, patients with major depression are excluded from the study

Age
From **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **21**
More than 1 sample in each individual
Number of samples in each individual: **1**
Each example is a Parkinson's patient with the ability to walk without crutches and the assistance of others

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method Randomization unit: individual Randomization tool: sealed envelope We write the numbers 1 to 21 on each paper and then each envelope is assigned to one person by lottery, and the numbers 1-4-7...are assigned to the first group, and the numbers 8-2-5-8...are assigned to the second group, and the numbers 9-3-6... They belong to the third group

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients in the study are blinded and do not know which group they are in. In the 2 treatment groups, the device is turned on, and in the control group, the device is turned off during rTMS application. The clinical caregiver is also blind in the study because he does not know about our grouping and he is only told for which patients to turn on the device and for which patients to turn off the device.

Placebo
Used

Assignment
Other

Other design features
In the study, we have 3 groups in which the same treatment (rTMS) is applied in 2 groups and we have a control group in which the rTMS device is applied off.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Semnan University of Medical Sciences

Street address
West Ferdous Blvd., Bahrashmali St., West Manochehri St., 1 Acacia Alley, No. 13, Zang 8

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Province
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Approval date
2023-01-24, 1401/11/04

Ethics committee reference number
IR.SEMUMS.REC.1401.255

Health conditions studied

1

Description of health condition studied
Parkinson's disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
1- The variable of hip-knee-ankle joint movement angles which is measured by the motion device

Timepoint
Before starting the intervention - the end of 10 treatment

sessions -1month follow-up

Method of measurement

three dimensional motion analysis device

2

Description

The variable of the movement score which is measured by the UPDRS-part 3 questionnaire

Timepoint

Before starting the intervention - the end of 10 treatment sessions -1month follow-up

Method of measurement

Questionnaire UPDRS-part 3

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The intervention is by rTMS device made by Madinatab Iran company and the evaluation is done by three dimensional motion analysis device and by Qualysis software and the intervention by rTMS device is in the form of 10 therapy sessions (3 sessions per week and 4 sessions at the end of the week) which is applied in the SMA group with a frequency of 10Hz in the M1 area with a pulse count of 2000 and a resting motor threshold intensity of 90%.

Category

Rehabilitation

2

Description

Intervention group:The intervention is by rTMS device made by Madinatab Iran and the evaluation is done by three dimensional motion analysis device and Qualysis software and the intervention by rTMS device is 10 treatment sessions (3 sessions per week and 4 sessions at the end of the week) which is applied in the DLPFC group with a frequency of 10 Hz in the F3 area with a pulse count of 2000 and a resting motor threshold intensity of 90%.

Category

Rehabilitation

3

Description

Control group: In the control group, the rTMS device is placed silently on the patients' heads so that the patients can use the visual and sensory feedback to receive the placebo treatment, and the patients' gait is evaluated before and after and as a 1-month follow-up by a three-dimensional motion analysis device and by the Qualysis software.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan University of Medical Sciences Research Center Clinic

Full name of responsible person

Majid Mirmohammadkhani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Ali Heidarinejad
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
People's information, including age and gender, can be published, but the names of people cannot be published
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Data must be used confidentially
From where data/document is obtainable
aliheidarinejad7444@gmail.com Ali heidarinejad 00989129345778
What processes are involved for a request to access data/document
After giving an email or a phone call to the mentioned phone number, the documents will reach her within 3 weeks

Comments