Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Assess the efficacy of Electroacupuncture vs. Sham Acupuncture on Gait in patients with Parkinson's Disease

Protocol summary

Study aim
Comparison of the effect of electroacupuncture compared to sham acupuncture in the gait disorder of Parkinson's patients

Design
The trial includes two groups, intervention and a sham control, with a parallel group, three blinded, randomized, phase 3 on 60 patients, randomization from randomaize.com.

Settings and conduct
The study is conducted in the specialized acupuncture clinic of Imam Reza Hospital in Mashhad. Patients diagnosed with Parkinson's disease are referred by neurologists from the Movement Disorders Clinic of Qayim Hospital. is. Then, depending on the allocation of the intervention or sham group, real or sham acupuncture is performed, which is two sessions a week for four weeks. And the initial evaluation is done again at the end of the fourth week and also at the twelfth week.

Participants/Inclusion and exclusion criteria
Patients with a definite diagnosis of Parkinson's disease by a neurologist who have Gait problems and are able to fill in the consent form to participate in the study. Having a movement disorder other than Parkinson's or coagulopathy, or having a pacemaker or DBS, or pregnancy prevents participation in the study.

Intervention groups
In the intervention group, electroacupuncture is performed at predetermined points with specific intensity, frequency and duration. In the control group, Streidberger needles are used, which look similar to acupuncture in the intervention group, but do not enter the skin, and are connected to the electro-acupuncture device for blinding, but without current.

Main outcome variables
Measurement of gait parameters single support time , double support time ,swing time،velocity ,cadence , stride length , stride time

General information

Reason for update
Acronym
-
IRCT registration information
IRCT registration number: **IRCT20170305032893N4**
Registration date: **2023-05-02, 1402/02/12**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-02, 1402/02/12**
Update count: **0**
Registration date
2023-05-02, 1402/02/12

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 0915
Email address
khorsanda@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-09, 1402/01/20
Expected recruitment end date
2023-10-12, 1402/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Assess the efficacy of Electroacupuncture vs. Sham Acupuncture on Gait in patients with Parkinson's Disease

Public title

The effect of electroacupuncture in Parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men/Women with parkinson diagnosis- walk for at least 10 meters without help-disease stable condition and no need to change dosage for two months-able to fillout consent form- no history of tratment of acupuncture fixed classic medicine regime treatment-parkinson with movment disorder- Hohen$Yar scale 1 to4

Exclusion criteria:

Gait disorder other than parkinson Life-threatening conditions, mental disorder, alcohol /drug abuse Electrical device/skin diseases interfere with electroacupuncture Change of drug dose /type for any reason during the study period Belonephobia Coagulation disorder and anticoagulant use Failure to cooperate in intervention for more than two sessions Pregnancy Patients with cardiac arrhythmia History of dementia or stroke History of cognitive disorders History of postural hypotension Neurological diseases such as Huntington's disease/MS, ALS History of epilepsy Acupuncture intolerance Having DBS(deep brain stimulation)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Randomaizer.com Except for the acupuncturist, everyone, including patients and health personnel, outcome assessors and data analysts, are all blind. First, the random numbers site is asked to divide and present 60 random numbers into two groups, A and B. Group A is the electroacupuncture intervention group and group B is the sham echopuncture group, and only the acupuncture interventional physician is aware of this division. The participants in the study after the referral from the neurologist and the initial assessment and filling out the forms are referred to the acupuncturist to perform the intervention or the sham according according to the assigned number and related group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants who do not know the type of intervention and do not know which group they are in. The outcome evaluator also has no knowledge of the type of intervention. The data analyst also only has access to the data and does not know about the groups and the intervention.

Placebo

Used

Assignment

Parallel

Other design features

The study is conducted in two intervention and sham acupuncture groups. The intervention group receives real acupuncture and the sham acupuncture group does not receive real acupuncture, and special STREITBERGER needles (needles designed for acupuncture control group) are used. It is exactly the same as real acupuncture without inserting needles into the body.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Razavi Khorasan Province, Mashhad, Daneshgah Ave

City

mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2022-11-06, 1401/08/15

Ethics committee reference number

IR.MUMS.REC.1401.257

Health conditions studied

1

Description of health condition studied

PARKINSON

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

The primary outcome includes the measurement of gait parameters :single support time , double support time , swing time , velocity , cadence ,stride length , stride time

Timepoint
Start of study, fourth week,twelfth week
Method of measurement
Video recording of walking and data analysis

Secondary outcomes

1

Description
Sleep problems based on the MDS-UPDRSI questionnaire.
Timepoint
At the beginning of the study and week 4 and week 12
Method of measurement
questionnaire

2

Description
Constipation problems based on the MDS-UPDRSI questionnaire
Timepoint
At the beginning of the study and week 4 and week 12
Method of measurement
questionnaire

3

Description
Fatigue based on the MDS-UPDRSI questionnaire
Timepoint
At the beginning of the study and week 4 and week 12
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Acupuncturist will perform acupuncture at predetermined and identical points for all participants in this group. And then the electrodes of the electroacupuncture device are connected to the needles for 20 minutes with an intensity of 1-3 mA and a frequency of 2-100 Hz. It is done twice a week for 4 weeks.
Category
Treatment - Devices

2

Description
Control group: Special Streitberger needles are used, which gives the patient exactly the sensation of true acupuncture, but the needle does not penetrate the skin. And it is performed by an acupuncturist in the non-acupuncture points . Also, similar to the intervention group, the electrodes of the electroacupuncture device are connected to the needles, but no current is established.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Movement disorder clinic of Qayim Hospital
Full name of responsible person
Ali Shoeibi
Street address
Neurology clinin , gaem Hospital , ahmadabad Blvd
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Mashhad
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Razavi Khorasan
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shoeibia@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobrahan
Street address
University Research and Technology Vice-Chancellor,3rd floor , University of Medical Sciences, next to Hoveizeh Cinema, University Street
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Province
Razavi Khorasan
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9138813944
Phone
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Email
GhayourM@mums.ac.ir
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
1
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

Babak Asadzadeh

Position

PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

Faculty of Iranian and Complementary Medicine. Second Floor. Faculty of Medicine. East Gate of Ferdowsi University. Mashhad. Khorasan Razavi

City

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Email

asadzadehb991@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Ali Khorsand vkilzadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Position

PhD student

Latest degree

Medical doctor

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Email

asadzadehb991@mums.ac.ir

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

Study specific information

When the data will become available and for how long

After completing the study and publish the result

To whom data/document is available

Project supervisors and persons who have permission from the University Research Council

Under which criteria data/document could be used

Only monitoring and not personal and research exploitation

From where data/document is obtainable

Academic council of the university

What processes are involved for a request to access data/document

Obtaining the opinion of the research council of the university and obtaining the favorable opinion of the researcher

Comments