

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of vibration orthosis in the cervical paraspinal muscles on dynamic balance and walking speed in patients with Parkinson's disease.

Protocol summary

Study aim

The effect of sensory mechanical stimulation in the form of neck vibration on walking speed

Design

This is a pre- and post -intervention study in which the samples will be randomly selected.

Settings and conduct

Patients are referred to the study after completing clinical assessments and completing the assessment on a Hoehn and Yahr scale. Biodex balance machine (Model 30 D_E6N_Sw45) in dynamic mode is used to evaluate patient balance. The overall stability index is a specific equilibrium measurement factor and is extracted by the output of the biodex balancing device, and in various situations without vibration orthosis, the vibration orthosis is closed with the motor off. And the light engine is compared. Evaluation of patients' walking speed is performed in three stages by Timed UP and GO test: without closing the vibrating neck orthosis, with vibrating orthosis while the motor is off, with vibrating orthosis while the motor is on . After the patient's initial examination for one month, he/she visits the Physical Medicine and Rehabilitation Department of Firoozgar Hospital for one month a week and receives electrical stimulation through vibration orthosis. Do the same with the methods mentioned above.

Participants/Inclusion and exclusion criteria

inclusion criteria : People 50-80 years with Parkinson's disease ,Being in one of stages 2 to 4 of the disease severity scale on the Hoehn and Yahr scale ,Having a stable medication regimen for at least the past 3 months
exclusion criteria : Having a history of falling in the past 6 months , other neurological or mental illnesses ,cardiovascular disease

Intervention groups

The vibration orthosis device is placed on the paraspinal cervical muscles of patients with Parkinson's disease and the patient walks with the device for 15 minutes.

Main outcome variables

overall stability index measured with biodex balance machine, Timed Up and Go test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190306042945N3**

Registration date: **2019-11-03, 1398/08/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-03, 1398/08/12**

Update count: **0**

Registration date

2019-11-03, 1398/08/12

Registrant information

Name

Bijan Forogh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2019-11-11, 1398/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vibration orthosis in the cervical paraspinal muscles on dynamic balance and walking speed in patients with Parkinson's disease.

Public title

The effect of vibration orthosis in the cervical paraspinal muscles on dynamic balance and walking speed in patients with Parkinson's disease.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People 50-80 years with Parkinson's disease Being in one of stages 2 to 4 of the disease severity scale on the Hoehn and Yahr scale Having a stable and specific medication regimen for at least the past 3 months

Exclusion criteria:

Having a history of falling in the past 6 months Having a history of other neurological or mental illnesses Having a history of cardiovascular disease Having musculoskeletal disease

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

committee of Iran University of Medical Sciences
Street address

Street address

Iran University of Medical Sciences ,Hemmat Highway
,Tehran

City

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Province

Tehran

Postal code

1449614535

Approval date

2019-01-16, 1397/10/26

Ethics committee reference number

IR.IUMS.FMD.REC.1397.248

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**

Dynamic Equilibrium Rate

Timepoint

zero ,4 weeks, 8 weeks

Method of measurement

Biodex Balancing Machine

2**Description**

Walking speed

Timepoint

zero ,4 weeks ,8 weeks.

Method of measurement

Timed Up and Go test

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

side effects

Timepoint

4 weeks ,8 weeks.

Method of measurement

physical examination

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

Intervention group: Vibration in the paraspinal cervical muscle area by inserting a vibrating orthosis in the Neck,
By researcher

Category

Treatment - Devices

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

Firoozgar hospital

Full name of responsible person

Fahime notghy

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Web page address**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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Fahime Notghi

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available