Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone

+98 21 8214 1612

Email address

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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 SciencesStreet addresse
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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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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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
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Fahime Notghi
Position
Resident of Physical Medicine and Rehabilitation
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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