

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of trans cranial direct current stimulation effect on balance, sleep quality, life quality and fatigue in Parkinson disease patients.

Protocol summary

Summary

Objectives: Evaluation of trans cranial direct current stimulation effect on balance, sleep quality, life quality and fatigue in Parkinson disease patients. Design: Patients with Parkinson disease after randomized selection based on study inclusion criteria by Physical Medicine and Rehabilitation specialist divides to two groups, anodal trans cranial direct current stimulation plus occupational therapy and sham anodal trans cranial direct current plus occupational therapy. Setting and conduct and intervention: Questionnaire is filled and then 8 sessions anodal trans cranial direct current plus occupational therapy is performed. Just after that and 3 months later questionnaires will be refilled and effects of this method on patient's balance, sleep quality, life quality and fatigue will be evaluated. Main outcome measures: balance, sleep quality, life quality and fatigue

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070123012N1**

Registration date: **2015-08-24, 1394/06/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-24, 1394/06/02

Registrant information

Name

Maryam Rafiei

Name of organization / entity

Iran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1229

Email address

maryam.rafiee.md@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of trans cranial direct current stimulation effect on balance, sleep quality, life quality and fatigue in Parkinson disease patients.

Public title

Evaluation of rehabilitation effect on balance, sleep quality, life quality and fatigue in Parkinson disease patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All of the patients should be in stage 2 or 3 of Parkinson disease based on Hoehn and Yahr criteria and also should: be under stable pharmacological treatment regime at least 30 days before entrance in study; be in stable clinical condition to complete the study; have appropriate primary response to Levo-DOPA or its agonist; not have Parkinson related dementia; not have abnormal MRI; not have drug related parkinsonism.

Exclusion criteria: patient unwillingness to complete the study; patient inability to complete the study because of any reason at any time during the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization with usage of enclosed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway, Tehran

City

Tehran

Postal code

Approval date

2014-08-20, 1393/05/29

Ethics committee reference number

93/d/105/3485

Health conditions studied

1

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson disease, Incl: Hemiparkinsonism, Paralysis agitans Parkinsonism or Parkinson disease: NOS, idiopathic, primary

Primary outcomes

1

Description

Balance

Timepoint

Before, just after 8 sessions of trans cranial direct current stimulation plus occupational therapy and 3 months later.

Method of measurement

Berge-Balance questionnaire

2

Description

Sleep quality

Timepoint

Before, just after 8 sessions of trans cranial direct current stimulation plus occupational therapy and 3 months later

Method of measurement

Epworth questionnaire

3

Description

Life quality

Timepoint

Before, just after 8 sessions of trans cranial direct current stimulation plus occupational therapy and 3 months later

Method of measurement

EQ-D5 questionnaire

4

Description

Tiredness

Timepoint

Before, just after 8 sessions of trans cranial direct current stimulation plus occupational therapy and 3 months later

Method of measurement

Fatigue severity scale questionnaire

Secondary outcomes

1

Description

Side effects

Timepoint

During and just after each session of trans cranial direct current stimulation performance

Method of measurement

Asking from a patient

Intervention groups

1

Description

8 sessions of trans cranial direct current stimulation with 2 Millie Ampere current during 20 minutes and then occupational therapy will be performed.

Category

Rehabilitation

2

Description

8 sessions of sham trans cranial direct current stimulation and then occupational therapy will be performed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Dr Maryam Rafiei

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Iran University of Medical Sciences

Full name of responsible person

Dr. Bijan Forogh

Street address

Physical Medicine and Rehabilitation department, Firoozgar hospital, Tehran,Iran

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research,Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Firoozgar hospital

Full name of responsible person

Dr. Maryam Rafiei

Position

Resident

Other areas of specialty/work

Street address

Physical Medicine and Rehabilitation, Firoozgar hospital, Valiasr square, Tehran

City

Tehran

Postal code

Phone

+98 21 8214 1229

Fax

Email

sunmarymoon@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Firoozgar hospital

Full name of responsible person

Dr. Bijan Forogh

Position

Physical Medicine and Rehabilitation specialist

Other areas of specialty/work

Street address

Physical Medicine and Rehabilitation, Firoozgar hospital, Valiasr square, Tehran

City

Tehran

Postal code

Phone

+98 21 8214 1229

Fax

Email

bijan.fr@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Firoozgar hospital

Full name of responsible person

Dr. Maryam Rafiei

Position

resident

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 21 8214 1229

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty