

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Assessment of effectiveness of short-term exercise therapy on functional capacity, balance and quality of life in patients with parkinson disease

Protocol summary

Summary

This study will be run by cooperation of neurology and sports medicine departments of Rasool akram hospital. Fifty patients with Parkinson Disease in defined condition will be referred from neurology clinic for exercise therapy. At first, all patients with PD will be evaluated with 6 -minute walk test for functional capacity and time up and go test for balance and all of them will fill out the questionnaire of Quality of Life SF. Then they will be divided randomly to two groups of control and intervention. Exercise therapy begin as standard protocol on treadmill in intervention group during 10 weeks and all of them will be evaluated in at the end of exercise therapy, 2- month and 4-month interval by tests and questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062322891N1**

Registration date: **2015-07-29, 1394/05/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-29, 1394/05/07

Registrant information

Name

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Name of organization / entity

Rasoul Akram hospital , Iran university of Medical Science

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-23, 1395/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of effectiveness of short-term exercise therapy on functional capacity, balance and quality of life in patients with parkinson disease

Public title

Effectiveness of exercise therapy on improvement of quality of life in patients with parkinson disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosed with Parkinson's Disease; being on phase (responsiveness to drug); being on moderate phase (UPDRS). Exclusion criteria: freezing gait; atypical Parkinson syndrome (progressive supranuclear palsy, multiple system atrophy, drug-induced etc.); have more than 2 risk factor for cardiovascular disease; significant osteoporosis or arthritis; other neurological disease/complications (e.g. myopathy, stroke, brain lesion, MS); history of significant cardiovascular accident or MI.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical science Ethics committee

Street address

Hemmat highway

City

Tehran

Postal code

Approval date

2015-06-14, 1394/03/24

Ethics committee reference number

IR.IUMS.rec.1394.8811215235

Health conditions studied

1

Description of health condition studied

Parkinson disease

ICD-10 code

G20

ICD-10 code description

Parkinsonism or Parkinson disease

Primary outcomes

1

Description

Functional Capacity

Timepoint

10 weeks after beginning of trial , 2 and 4 month after

finishing trial

Method of measurement

6-minute Walk test , SF-8 quality of Life Questionnaire

2

Description

Balance

Timepoint

10 weeks from beginning of trial , 2 and 4 month after trial

Method of measurement

Up and go test

3

Description

Quality of Life

Timepoint

10weeks after beginning of trial , 2 and 4 months after finishing the trial

Method of measurement

8-SF Questionnaire Quality of Life

Secondary outcomes

1

Description

Activity of Daily Life

Timepoint

2 and 4 months after study

Method of measurement

6- minute walk test

Intervention groups

1

Description

intervention name : Exercise Therapy and drug therapy
intervention description : patients with mid phase PD that have been on drug treatment , Levodopa, will be undergone exercise therapy on treadmill 3 times a week with mild to moderate intensity 30 to 50 minutes every session for 10 weeks

Category

Other

2

Description

Intervention name : drug therapy Control group : patients with midphase Parkinson disease are on Levodopa treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Nerology Clinic in

Full name of responsible person

Dr Amirhassan Habibi

Street address

Rasoul Akram Hospital, Shahrara, Sattar Khan st.

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Afsaneh Safar Cherati

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Rasoul hospital, Sattaer Khan avenue

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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*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**

Iran university of medical sciences

Full name of responsible person

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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*