Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Clinical trial of the effect of curcumin supplementation plus resistance training compared with the placebo on disease severity and metabolic profiles in patients with Parkinson's

Protocol summary

Study aim
The aim of this study is to determine the effects of curcumin supplementation plus resistance training compared with the placebo on disease severity and metabolic profiles in patients with Parkinson's.

Design
This study is a open labeled randomized controlled clinical trial.

Settings and conduct
Neurology clinic of Shahid Beheshti hospital, Kashan, Iran Sport club, Kashan, Iran

Participants/Inclusion and exclusion criteria
Inclusion criteria: Grade 2 and 3 Parkinson disease patients ; aged 18 to 50 Exclusion criteria: 1- Patients suffering from cardiovascular, hepatic, or kidney diseases, 2- Patients taking antioxidant and/or anti-inflammatory supplements. 3- People who had regular exercise at least 3 1 month before this trial. 4- People who smoke. 5- patients with hypo/hyperthyroidism or any other metabolic disorders.

Intervention groups
1- Intervention group; intake 2 curcumin capsules per day (1000 mg/day) for 8 weeks.(n=10) 2- Intervention group; have resistance training 3 times per week for 8 weeks.(n=10) 3- Intervention group; have resistance training 3 times per week and intake 2 curcumin capsules per day (1000 mg/day)for 8 weeks.(n=10) 4- Control group; intake placebo (2 capsule per day). (n=10)

Main outcome variables
Clinical status of patients assessed by Unified Parkinson's Disease Rating Scale (UPDRS) questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191231045968N1**
Registration date: **2020-07-20, 1399/04/30**
Registration timing: **retrospective**

Last update: **2020-07-20, 1399/04/30**
Update count: **0**

Registration date
2020-07-20, 1399/04/30

Registrant information

Name
Zahra Zabihi Rezaei

Name of organization / entity
Kharazmi University

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-06, 1399/03/17

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of curcumin supplementation

plus resistance training compared with the placebo on disease severity and metabolic profiles in patients with Parkinson's

Public title
The effect of curcumin supplementation plus resistance training in treatment of patients with Parkinson's
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Parkinson's Aged 50 to 80 years
Exclusion criteria:
Taking antioxidants supplements Taking anti-inflammatory supplements Depression Severe psychosis hypo- and hyperthyroidism Smoking Consuming curcumin supplements within 3 month prior to the study Restrictions to practicing exercise, including cardiovascular disease, stroke, respiratory problems and any surgical procedures for the treatment of PD e.g., deep brain stimulation (DBS). Motor deficits that could limit performance in exercise in the study Practicing any regular physical activity except for resistance training in the study.
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline, participants based on balanced blocked randomization will be allocated into four groups to take either curcumin supplementation plus resistance training (n=10), curcumin supplementation (n = 10), resistance training (n=10) or placebo (n = 10). Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features
The patients and researchers have direct connection in order to performing the exercises thus, this study is not blinded. This work is a open labeled study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kharazmi University
Street address
Kharazmi University, South Moffateh st, Tehran
City
Tehran
Province
Tehran
Postal code
1571914911
Approval date
2019-11-03, 1398/08/12
Ethics committee reference number
IR.KHU.REC.1398.028

Health conditions studied

1

Description of health condition studied
Parkinson disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Unified Parkinson's disease rating scale
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
Physical Examination by Neurologist

Secondary outcomes

1

Description
Insulin
Timepoint
At the beginning of the study and after 8 weeks of intervention
Method of measurement
ELISA kit

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 8 weeks of

intervention

Method of measurement

Calculation using HOMA formula

3

Description

Triglycerides

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

Total cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

6

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

7

Description

Fasting blood sugar

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Enzymatic kit

8

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Glutathione

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

10

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 8 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

500 mg curcumin capsule (contain 450 mg turmeric powder and 50 mg tumeric concentration equivalent with 47.5 mg curcumin) twice a day, for 8 weeks. Exercises are designed in format of 3 circles in each session. The main exercise will be designed with variable intensity suitable with person's ability. The equipment includes leg extension and flexion machine, under hand cable pull down, chest press, shoulder press, elbow extension and flexion machine. The exercises are designed for 3 times per week (60 min for each time) for 8 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Resistance training (three times a week) for 8 weeks.

Category

Treatment - Other

3

Description

Intervention group: 500 mg curcumin capsule twice a day plus resistance training (three times a week) for 8 weeks.

Category

Treatment - Other

4

Description

Control group: Without resistance training and the consumption of curcumin supplementation

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Neurology Clinic
Full name of responsible person
Dr Reza Daneshvar
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Sponsors / Funding sources

1

Sponsor

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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
Kharazmi University

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
Kharazmi University
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Pejman Motamedi
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Assistant Professor
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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