

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 an 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 months 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)

Phone

+98 31 5558 3545

Email address

std_zahra.zabihi@khu.ac.ir

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 an 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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5562 0608

Email

daneshvar-r@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Jamshid Shanbehzadeh

Street address

South Mofatteh Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1571914911

Phone

+98 21 8607 0779

Email

jamshid@khu.ac.ir

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

Full name of responsible person

Pejman Motamedi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Physiology

Street address

South Mofatteh Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1571914911

Phone

+98 26 3451 2001

Email

Pezhman.Motamedi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person

Pejman Motamedi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

South Mofatteh Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1571914911

Phone

+98 26 3451 2001

Email

Pezhman.Motamedi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kharazmi University

Full name of responsible person

Zahra Zabihi Rezaei

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiology

Street address

South Mofatteh Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1571914911

Phone

+98 26 3455 0702

Email

Std_zahra.zabihi@khu.com

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