

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Ganoderma Leucidum Extract and Eight-Week Endurance Exercise on Selection of Antioxidant Indicators and Growth Factors and Nervous Mediators in Parkinson's Old Men

Protocol summary

Study aim

Determination of the effect of ganoderma extract and eight weeks of endurance training on a selection of plasma antioxidant and neurological indicators in men with Parkinson's

Design

Clinical trial with control group, with parallel, randomized group, phase 2 on 24 patients. The rand function of the Excel software was used for randomization.

Settings and conduct

This research is a semi-experimental clinical trial in which the preliminary (pre-test) and final (post-test) test schemes will be used. Be. The statistical population of this study will be all patients with Parkinson's disease in Ardabil University of Medical Sciences, which is 86 people in this university.

Participants/Inclusion and exclusion criteria

For this purpose, 24 qualified men were randomly selected with the opinion of a specialist physician and randomly assigned to four control groups or placebo (6 people), exercise, supplement and exercise-supplement.

Intervention groups

Four control groups or placebo (6 people), exercise (6 people), supplement (6 people) and exercise + supplement (6 people)

Main outcome variables

Endurance training; Ganoderma extract supplement; Antioxidant indicators; Plasma nerve; Parkinson

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200708048053N1**

Registration date: **2020-08-12, 1399/05/22**

Registration timing: **retrospective**

Last update: **2020-08-12, 1399/05/22**

Update count: **0**

Registration date

2020-08-12, 1399/05/22

Registrant information

Name

farshid ganji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3252 6348

Email address

ganji.farshid1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

2019-12-11, 1398/09/20

Actual recruitment end date

2020-03-10, 1398/12/20

Trial completion date

2020-03-20, 1399/01/01

Scientific title

The Effect of Ganoderma Leucidum Extract and Eight-Week Endurance Exercise on Selection of Antioxidant Indicators and Growth Factors and Nervous Mediators in Parkinson's Old Men

Public title

The Effect of Ganoderma Leucidum Extract and Eight-Week Endurance Exercise on Selection of Antioxidant

Indicators and Growth Factors and Nervous Mediators in Parkinson's Old Men

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Using Parkinson's, which can be told by a doctor for 3 years at level 3, you can measure Y&H. at level 3, you can measure Y&H. Be in the age range of 40-60 years
Exclusion criteria:
 Patients who were unable to perform their daily activities

Age
From **40 years** old to **60 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
 Target sample size: **24**
 Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
 Random assignment to intervention and control groups
 The randomization method is simple randomization and the randomization unit is individual. Randomization and random sequencing will be performed using a web-based randomization system (<https://www.graphpad.com/quickcalcs/randMenu>). Hide group assignments will be done using numbered consecutive sealed envelopes.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Simultaneous intervention of exercise and Ganoderma extract was applied to Parkinson's patients

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Islamic Azad University - Marvdasht
Street address
 ST Takht Jamshid
City
 Marvdasht
Province
 Fars
Postal code

7371113119
Approval date
 2020-06-09, 1399/03/20
Ethics committee reference number
 IR.IAU.M.REC.1399.016

Health conditions studied

1

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

Primary outcomes

1

Description
 Antioxidant indicators (total antioxidant capacity) in men with Parkinson's disease

Timepoint
 24 hours before the intervention and 24hours after the sports and medical intervention

Method of measurement
 Serum level of total antioxidant capacity using TAC assay laboratory kit made by Pars Azmon Company and ELISA method

2

Description
 Plasma neuronal levels (NGF factor, dopamine, serotonin, BDNF, tyrosine hydroxylase) in men with Parkinson's

Timepoint
 24 hours before the intervention and 24hours after the sports and medical intervention

Method of measurement
 1. NGF factor by ELISA method and using special NGF Elisa Kit made in China with a sensitivity of 2.48 picograms per ml A2. Dopamine by ELISA method using LDN kit made by Pars Azmoun Company of Iran 3. Tyrosine hydroxylase level by ELISA method and by laboratory kit of Pars Azmoun Company of Iran 4. BDNF factor by ELISA method and using special kit (Human BDNF) Made in China with a sensitivity of 2 picograms per milliliter 5. Serotonin by ELISA method and LSD kit made by Pars Azmoun Company in Iran

Secondary outcomes

empty

Intervention groups

1

Description
 Control group: 6 Parkinson's male patients- No

intervention will be performed in the control group

Category

Placebo

2

Description

Intervention group: Training group of 6 patients with Parkinson's disease- The 8-week training program will be supervised three times a week under the supervision of a sports physiologist. Endurance training includes walking at a speed of 4 km / h to 8 km / h with an intensity of 50 to 65% of the maximum heart rate, the first 10 minutes will include warming up the main muscles of the body and the last 10 minutes will be considered as recovery. One week before the training contract, the objectives and method of conducting the research will be clearly explained to the subjects and then special consent forms will be provided to them. After entering the gym, the subjects will start warming up for 10 minutes. Which includes doing stretching movements. Subjects will then begin to walk at a speed of 4 km / h with an intensity of 50% of maximum heart rate. The intensity and duration of the activity will gradually increase, depending on the ability of the patients, so that in the 12th week, the walking speed will reach 8 km / h with a maximum intensity of 65% of the heart rate. At the end of the training session, a general cooling will be performed for 10 minutes.

Category

Treatment - Other

3

Description

Intervention group: Supplement (Ganoderma extract) 6 Parkinson's male - Intervention group: Supplement (Ganoderma lucidum extract) 6 patients with Parkinson's disease - Ganoderma lucidum extract manufactured by Bayes company and approved by the Food and Drug Administration and prepared according to the weight of individuals (Supplementary group: 6 mg Ganoderma lucidum powder per kg of body weight) So that the amount of Ganoderma consumed in the present study, according to the results of previous studies (Zee Liren et al., 2018) in the effective range (3-9 mg per kg of body weight, 30-60 minutes before the training contract) Will be required to improve the plasma level and performance of the subjects.patients

Category

Treatment - Other

4

Description

Intervention group: Exercise + Supplement 6 Parkinson's male patients - They will do an endurance training program for eight weeks and three sessions per week - Ganoderma lucidum extract made by Bayes company and approved by the Food and Drug Administration and prepared according to weight Individuals (supplement group: 6 mg Ganoderma lucidum powder per kilogram of body weight) will be given to the subjects 45 minutes

before the training contract. So that the amount of Ganoderma consumed in the present study, according to the results of previous studies (Zee Liren et al., 2018) in the effective range (3-9 mg per kg of body weight, 30-60 minutes before the training contract) Will be required to improve the plasma level and performance of the subjects.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ardabil University of Medical Sciences

Full name of responsible person

Dr Mohammad RazmAfrooz

Street address

St Khayam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Alireza Barari

Street address

Amol - 5 km of the old road from Amol to Babol -
University Branch - Islamic Azad University, Ayatollah
Amoli Branch

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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

Islamic Azad University

Proportion provided by this source

30

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Farshid Ganji

Position

PhD Student in Sports Physiology

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Alireza Barari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

PhExercise Physiology Cardiovascular and Respiratory

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Alireza Barari

Position

Assistant Professor Ayatollah Amoli Azad University

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Postal code

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/documentTotal potential data after unrecognizable shared people
It's laying.**When the data will become available and for how long**Start the access period 6 months after printing the
results**To whom data/document is available**Data will only be available to researchers working at
academic and scientific institutions.

Under which criteria data/document could be used

Various analyzes are allowed for researchers working in academic and scientific institutions.

From where data/document is obtainable

Farshid Ganji - Ardabil Province - Meshkinshahr - Jomhuri St. in front of Etkā Store - 09144580525 -

5661844347 - ganji.farshi1@gmail.com

What processes are involved for a request to access data/document

Send a request via email - Data submission time: two weeks

Comments