Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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

City

Meshkinshahr

Province

Ardabil

Postal code

5661844347

Phone

+98 45 3254 4375

Email

mahtab.nobakht2016@gmail.com

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

City

Amol

Province

Mazandaran

Postal code

678

Phone

+98 11 4321 7000

Email

info@iauamol.ac.ir

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
Street address
St Jomhori
City
Meshkin Shahr
Province
Ardabil
Postal code
5661844347
Phone
+98 45 3254 4375
Email
ganji.farshid1@gmail.com

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
Street address
Amol - 5 km of the old road from Amol to Babol - University Branch - Islamic Azad University, Ayatollah Amoli Branch
City
Amol
Province
Mazandaran
Postal code
678
Phone
+98 11 4321 7000
Email
Alireza54.barari@gmail.com

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
Street address
Amol - 5 km of the old road from Amol to Babol - University Branch - Islamic Azad University, Ayatollah Amoli Branch
City
Amol
Province
Mazandaran
Postal code
3358-461514
Phone
+98 11 4321 7000
Fax
+98 11 4321 7043
Email
alireza54.barari@gmail.com
Web page address

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/document
Total 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 - Jomhouri St. in front of Etka 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