Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of supplementation with Ganoderma lucidum on anthropometric indices,chemical biomarkers and blood pressure of people with overweight

Protocol summary

Study aim

the effect of Ganoderma lucidum supplementation on anthropometric indices, chemical biomarkers and blood pressure in overweight people

Design

A clinical trial with a control group, with a parallel, double-blind, randomized, phase 3 group on 72 patients, used the rand function of Excel software for randomization.

Settings and conduct

The study was performed in Salahuddin Ayoubi Hospital in Baneh. They were randomly divided into two groups of intervention and control. Patients who were eligible for the study were randomly divided into two groups of placebo and medicine. Whether the drug was a placebo or an intervention was unknown but the researcher was aware. Patients and drugs were coded by the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age 60 to 18 years, personal satisfaction,Body mass index 25 to 29.9, no underlying diseases interfering with weight loss and drug use, use of any type of weight loss and fat or blood pressure monitor and blood sugar control, non-pregnancy and lactation.Exclusion criteria:taking Weight loss supplements,following a diet to lose weight,diseases associated with metabolic changes such as thyroid disease,taking drug that inhibit platelet aggregation (such as aspirin or warfarin) ,unavailability of any reason

Intervention groups

Intervention group: Patients received 3 capsules of Ganoderma daily, each capsule containing 220 mg of complete powder of Ganoderma lucidum and 30 mg of pure aqueous extract of Ganoderma lucidum for 6 weeks. Control group: Patients received 3 capsules daily, each containing 250 mg of wheat flour for 6 weeks.

Main outcome variables

Body mass index(BMI) , weight, waist circumference, hip circumference, waist to hip ratio, arm circumference, total cholesterol concentration,Low density lipoprotein(LDL),High density lipoprotein(HDL) , triglyceride, blood sugar, blood pressure,Physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N7**
Registration date: **2020-12-26, 1399/10/06**
Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**
Update count: **0**

Registration date

2020-12-26, 1399/10/06

Registrant information

Name
MARYAM SHIEHMORTEZA
Name of organization / entity
AZAD UNIVERSITY PHARMACEUTICAL SCIENCES
Country
Iran (Islamic Republic of)
Phone
+98 212640056
Email address
shiehmorteza@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-05, 1399/03/16

Expected recruitment end date

2020-07-18, 1399/04/28

Actual recruitment start date
2020-06-05, 1399/03/16
Actual recruitment end date
2020-07-24, 1399/05/03
Trial completion date
2020-07-24, 1399/05/03

Scientific title
The effect of supplementation with Ganoderma lucidum on anthropometric indices,chemical biomarkers and blood pressure of people with overweight

Public title
The effect of Ganoderma lucidum on weight and chemical biomarkers and blood pressure in overweight people
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having an age of 18-60 years personal satisfaction BMI between 29.9-25 no underlying diseases interfering with weight loss and drug use taking any type of weight loss and fat or blood pressure monitor and blood sugar controller no pregnancy And breastfeeding
Exclusion criteria:
Taking weight loss supplements following a diet to lose weight diseases related to metabolic changes such as thyroid disease pregnancy and lactation, taking drugs that inhibit platelet aggregation (such as aspirin or warfarin) due to drug interactions unavailability of any a reason
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling was done by simple random sampling so that 72 people were selected using a random table of numbers and randomly assigned by random numbers by random numbers in Exel software were divided into two groups of intervention and control (default: numbers Pairs in Ganoderma supplement group = intervention group and individual numbers in group of capsules filled with wheat flour = in control group)
Blinding (investigator's opinion)
Double blinded
Blinding description
All patients who were eligible for the study were randomly divided into placebo and drug groups. Patients and laboratory staff and physicians were unaware of the intervention drug or placebo. But the researcher knew whether the intervention was drug or placebo. And the drugs were coded by the researcher. The dressing was such that the placebo was the same shape, color, and taste of the drug. That is, the drug and the placebo were both similar in appearance. But the placebo capsules contained wheat flour.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University of Medical Sciences, Tehran
Street address
Paint Factory Deadlock, Attari Moghadam St , Shahid Khaghani St , Islamic Azad University of Tehran Medical Branch , Research Office
City
TEHRAN
Province
Tehran
Postal code
1958
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.IAU.PS.REC.1399.151

Health conditions studied

1

Description of health condition studied
overweight
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Body mass index (BMI)
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
math formula

2

Description
Weight
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
digital Balance

3

Description
Arm circumference
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Tape meter

4

Description
Hip circumference
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Tape meter

5

Description
Waist
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Tape meter

6

Description
Waist to hip
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
math formula

7

Description
blood pressure
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Digital sphygmomanometer

8

Description
Total cholesterol
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Direct enzymatic

9

Description
triglyceride
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Direct enzymatic

10

Description
High density lipoprotein (HDL)
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Direct enzymatic

11

Description
Low density lipoprotein (LDL)
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Direct enzymatic

12

Description
Blood sugar
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
Direct enzymatic

13

Description
Physical activity
Timepoint
Before the start of the study and 42 days after starting to take Ganoderma capsules
Method of measurement
International Physical Activity Questionnaire (IPAQ)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group received 3 Ganoderma supplement capsules per day, each capsule containing 220 mg of complete powder of Ganoderma lucidum and 30 mg of pure aqueous extract of Ganoderma lucidum.
Category
Treatment - Drugs

2

Description
Control group: This group received 3 capsules a day, each capsule containing 250 mg of wheat flour as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baneh salahaddin ayubi hospital
Full name of responsible person
Amine babamiri
Street address
Saat street
City
Baneh
Province
Kurdistan
Postal code
5676677544
Phone
+98 87 5426 0000
Email
Dr.babamiri.shilan@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr.farshad hashemian
Street address
Shariati St , Khaghani St , Islamic Azad University of Medical Sciences , Tehran
City
Tehran
Province
Tehran
Postal code
1941933111
Phone
+98 21 2200 6660
Fax
+98 21 2260 0714
Email
info@iau.ac.ir
Web page address
http://iaups.iautmu.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad 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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Amine babamiri
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Abuzar street
City
Bukan
Province
West Azarbaijan
Postal code
59518039574
Phone
0098 44 6247630
Email
dr.babamiri.shilan@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
amineh babamiri
Position
student
Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy
Street address
abuzar
City
bukan
Province
West Azarbaijan
Postal code
59518039574
Phone
0098 446247630
Email
dr.babamiri.shilan@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
maryam shiehmorteza
Position
Doctor f Pharmacotherapy
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Dr. Shariati St., Gholhak St., Islamic Azad University, Pharmaceutical Sciences Branch
City
Tehran
Province
Tehran
Postal code
194193331
Phone
+98 21 2264 0051
Email
shiehmorteza@iaups.ac.ir

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