

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Effects of Ganoderma lucidum on laboratory change in Non alcoholic fatty liver disease patient in 12 week clinical trial

Protocol summary

Study aim

Effects of Ganoderma lucidum on laboratory change in Non alcoholic fatty liver disease patient

Design

In a randomised, double-blind, controlled clinical trials 80 patients will randomly assigne in the control and intervention groups.

Settings and conduct

Among patients admitted in medical ward of Kowsar hospital, Semnan who fullfil in clusion criteria, Intervention group receive 3 capsules daily containing whole powder of Ganoderma lucidum, 220 mg; pure aqueous extract of Ganoderma lucidum, 30 mg standardized based on 17 micrograms per 1 mg total polysaccharide and control group receive only routine treatment. It is mentioned to patients that follow exercise programs and a low-fat diet. The laboratory test including CBC diff, BUN, Cr, ALT, AST, FBS will be done at the beginning of the study by the end of the twelfth week

Participants/Inclusion and exclusion criteria

Age 20 to 60 year Fatty liver in sonography ALT over40 Satisfied patient Cardiac disease Familial hyper lipidemia Over weight with bmi over 30 Acute systemic disease(renal or galblader stone) Cardiac surgery Abdomina surgery CVA Hepatitis Pancrititis Hemochromatosis Wilson's disease Autoimmune hepatitis Chronic liver disease Surgery in past 6 month Liver or galblader surgery Weith loss in 3 past month Alcohol user Sensivity to mushroom Drug related fatty liver

Intervention groups

Intervention group receive 3 capsules daily containing whole powder of Ganoderma lucidum, 220 mg; pure aqueous extract of Ganoderma lucidum, 30 mg standardized based on 17 micrograms per 1 mg total polysaccharide. Patients in control group receive only routine treatment.

Main outcome variables

Serum alanine aminotransferase (ALT), aspartate

aminotransferase (AST), , total cholesterol (TC), triglyceride (TG), low density lipoprotein (LDL) and high-densitylipoprotein (HDL) levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191217045763N1**

Registration date: **2020-11-29, 1399/09/09**

Registration timing: **retrospective**

Last update: **2020-11-29, 1399/09/09**

Update count: **0**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

Hanif Hashemnejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5522 0373

Email address

hashemnejad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-22, 1398/11/02

Expected recruitment end date

2020-04-21, 1399/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Effects of Ganoderma lucidum on laboratory change in Non alcoholic fatty liver disease patient in 12 week clinical trial

Public title
Ganoderma lucidum in Non alcoholic fatty liver disease patient

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient referred to gastroenterology clinic of semnan kosar hospital Diagnose is Non alcoholic fatty liver disease Don't receive treatment yet

Exclusion criteria:

No sonographic change for fatty liver Alcoholic fatty liver Other liver disease

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Ave.

City

Semnan

Province

Semnan

Postal code
35147-99442

Approval date
2019-12-17, 1398/09/26

Ethics committee reference number
IR.SEMNAN.RES.1398.225

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

DB92

ICD-10 code description

Non-alcoholic fatty liver disease

2

Description of health condition studied

Fatty liver disease

ICD-10 code

DB92.Z

ICD-10 code description

Non-alcoholic fatty liver disease, unspecified

Primary outcomes

1

Description

Effects of Ganoderma lucidum on ALT in Non alcoholic fatty liver disease patient

Timepoint

12 week

Method of measurement

Laboratory Reference

2

Description

Effects of Ganoderma lucidum on AST in Non alcoholic fatty liver disease patient

Timepoint

12 week

Method of measurement

laboratory Reference

Secondary outcomes

1

Description

CHOLESTROL

Timepoint

12 week

Method of measurement

Laboratory reference

2

Description

LDL

Timepoint

12week

Method of measurement

Laboratory reference

3

Description

HDL

Timepoint

12 week

Method of measurement

Laboratory reference

Intervention groups

1

Description

Intervention group receive 3 capsules daily containing whole powder of Ganoderma lucidum, 220 mg; pure aqueous extract of Ganoderma lucidum, 30 mg standardized based on 17 micrograms per 1 mg total, produced by Ki Daroo Technology Company, the Ministry of Health license code 1681449932720180. It is mentioned to patients that follow exercise programs and a low-fat diet. The laboratory test including CBC diff, BUN, Cr, ALT, AST, FBS will be done at the beginning of the study by the end of the twelfth week

Category

Treatment - Drugs

2

Description

Control group: receive reutin treatment. It is mentioned to patients that follow exercise programs and a low-fat diet. The laboratory test including CBC diff, BUN, Cr, ALT, AST, FBS will be done at the beginning of the study by the end of the twelfth week.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Hanif Hashemnejad

Street address

Basij Ave

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kosarhos@semums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr.Reza Dabiri

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Email

Dabirirzf@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

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

Semnan University of Medical Sciences

Full name of responsible person

Hanif Hashemnejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
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Position
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Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Hanif Hashemnejad
Position
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Latest degree

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Some information

When the data will become available and for how long

6 month after article publication

To whom data/document is available

All

Under which criteria data/document could be used

With reference

From where data/document is obtainable

E-mail

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

In 15 day with my E-mail

Comments