Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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

Iñ a randomised, double-blind, controled 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 reutine 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 reutine 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 refered to gastroentrology 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: recieve reutin tratment. 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Dr.Reza Dabiri
Street address
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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 updating data

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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 publition

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