

# 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

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

##### Phone

+98 23 3142 2120

##### Fax

+98 23 3142 2121

##### Email

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

##### Street address

Basij Ave

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

##### Phone

+98 23 3142 2120

##### 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

##### Street address

Basij Ave  
**City**  
Semnan  
**Province**  
Semnan  
**Postal code**  
3519899951  
**Phone**  
+98 23 3142 2120  
**Email**  
Hashemnejad@gmail.com

## Person responsible for scientific 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  
**Street address**  
No. 88, Zeytoon 7th, Tohid 16th, Janbazan Boulevard  
**City**  
Babol  
**Province**  
Mazandaran  
**Postal code**  
4718766389  
**Phone**  
+98 11 5522 0373  
**Fax**  
**Email**  
Hashemnejad@gmail.com

## Person responsible for updating data

### 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  
**Street address**  
No. 88, Zeytoon 7th, Tohid 16th, Janbazan Boulevard  
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Babol  
**Province**  
Mazandaran  
**Postal code**  
4718766389  
**Phone**  
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**Fax**  
**Email**  
Hashemnejad@gmail.com

## 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