

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of the effect of Ganoderma lucidium and Kambucha on blood sugar in patients with type 2 diabetes

#### Protocol summary

##### Study aim

Comparison of the effect of Ganoderma lucidium and Cambodia on blood sugar in patients with type 2 diabetes

##### Design

Clinical trial with control group, with parallel, randomized groups, on 75 patients.

##### Settings and conduct

In this study, a group of type 2 diabetic patients referred to the diabetes clinic of Qazvin city hospital enter the study. The first group, in addition to the previous oral anti-diabetic drugs, 1 gram per day in the first week, 2 grams per day in the second week and From the Next second week, 3 grams per day of pure Ganoderma mushroom powder can be used .The second group of intervention can drink a glass of kambucha in the first week and From the Next second week can drink 2 glasses of kambucha a day after meals. In the third group, which is the control group, Continuation of medical treatment will be followed by the previous method.

##### Participants/Inclusion and exclusion criteria

75 patients with type 2 diabetes who Inclusion criteria : They took oral antidiabetic drugs and had fasting blood sugar greater than or equal to 140 mg / dL and less than 200 mg / dL and exclusion criteria: No side effects such as retinopathy, proliferative, creatinine above 2.1 and triglyceride above 40 mg / dL, selected.

##### Intervention groups

The first group, in addition to the previous oral anti-diabetic drugs, 1 gram per day in the first week, 2 grams per day in the second week and From the Next second week, 3 grams per day of pure Ganoderma mushroom powder can be used .The second group of intervention can drink a glass of kambucha in the first week and From the Next second week can drink 2 glasses of kambucha a day after meals. In the third group, which is the control group, Continuation of medical treatment will be followed by the previous method.

##### Main outcome variables

Patients' fasting blood sugar, blood sugar 2 hours after a meal

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190919044819N3**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **prospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

##### Registration date

2020-10-26, 1399/08/05

##### Registrant information

##### Name

narges hosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7768 4704

##### Email address

nargeshossini123@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-19, 1399/12/29

##### Expected recruitment end date

2023-01-10, 1401/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of Ganoderma lucidium and Kambucha on blood sugar in patients with type 2 diabetes

**Public title**

Comparison of the effect of Ganoderma lucidium and Kambucha on blood sugar in patients with type 2 diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

With type 2 diabetes with fasting blood sugar between 140 and 200 mg / dL Be over 18 years old Assessment tools to fully understand the instructions. Read and sign informed consent. Not using of immunosuppressive drugs(Kambucha drink can activate the immune system.) Not using Anticoagulant therapy Not having neuropsychological, cognitive diseases Not having cardiac diseases Not having renal diseases Not having Allergic history Not having retinopathy Not having Creatinine above 1.2 mg / dL Not having Triglycerides above 40 mg / dL

**Exclusion criteria:**

Insulin consumption Is pregnant or suspected pregnancy Participation in another study that could affect results

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals are randomly assigned to one of three study groups using a table of random numbers From 75 people, three groups of 25 items should be selected as a sample, we should first give each of them as a member of the community a two-digit code (01, 02, 03, ..., 75). Then go to the table, select the starting point and move in the direction of the row or column based on the adjacent two-digit numbers. We choose the first two-digit number less than 75 as the first example and ignore numbers greater than 75. He goes on to do this until we can select three groups of 25 cases as examples.

**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 Qazvin University of Medical Sciences

**Street address**

Shahid Bahonar Boulevard, Qazvin University of Medical Sciences

**City**

gazvin

**Province**

Qazvin

**Postal code**

34417431874

**Approval date**

2020-09-05, 1399/06/15

**Ethics committee reference number**

IR.QUMS.REC.1399.207

**Health conditions studied****1****Description of health condition studied**

Patients with type 2 diabetes

**ICD-10 code**

E08

**ICD-10 code description**

Diabetes mellitus due to underlying condition

**Primary outcomes****1****Description**

Fasting blood sugar

**Timepoint**

Fasting blood sugar will be measured and analyzed at the first visit and also after the end of 6 weeks of treatment.

**Method of measurement**

Glucometer

**2****Description**

Glucose two hours after a meal

**Timepoint**

Glucose two hours after a meal will be measured and analyzed at the first visit and also after the end of 6 weeks of treatment.

**Method of measurement**

Glucometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group1: In addition to the previous oral antidiabetic drugs, the first group can consume 1 gram per day in the first week, 2 grams per day in the second week, and from the second week onwards, 3 grams per day of pure Ganoderma mushroom powder. Mix Ganoderma mushroom powder as a drink with a glass of boiling water and use it after meals.

#### Category

Treatment - Other

### 2

#### Description

Control group: In the third group, which is the control group, the continuation of drug treatment as before will be followed. The studied patients will be treated with glibenclamide and metformin in the same groups.

#### Category

Treatment - Other

### 3

#### Description

Intervention group2: The second group can drink one cup of kombucha in the first week and 2 cups of kombucha a day after meals from the second week onwards.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabetes Clinic of Velaiah Hospital

##### Full name of responsible person

Leili Yekefallah

##### Street address

Qazvin University of Medical Sciences,  
Bahonar, Qazvin, Iran

##### City

Qazvin

##### Province

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##### Postal code

34411743148

##### Phone

+98 28 3333 6001

##### Email

Leili\_fallah@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Mahdi Emamjomeh

##### Street address

Qazvin University of Medical Sciences,  
Bahonar, Qazvin, Iran

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##### Province

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##### Phone

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##### Email

Apeymani@qums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

##### Full name of responsible person

Leili Yekefallah

##### Position

Assistant Professor of Qazvin Nursing School

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

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**Name of organization / entity**

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**Full name of responsible person**

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**Email**

Leili\_fallah@yahoo.com

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Comparison of the effect of Ganoderma lucidium and Cambodia on blood sugar in patients with type 2 diabetes

**When the data will become available and for how long**

6 months after printing the results

**To whom data/document is available**

Qazvin University of Medical Sciences

**Under which criteria data/document could be used**

Through a valid university site

**From where data/document is obtainable**

Qazvin- Qazvin University of Medical Sciences- School of Nursing and Midwifery

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

Send authors email

**Comments**