

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 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

AgeFrom **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

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Qazvin University of Medical Sciences,
Bahonar, Qazvin, Iran

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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

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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

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Person responsible for updating data

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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