

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Evaluation of the effect of Ganoderma lucidum (with usual diabetes medications) on blood glucose control in type 2 diabetic patients: A placebo-controlled double-blind clinical trial

Protocol summary

Study aim

To determine the effect of Ganoderma in the glycaemic control in diabetes patients

Design

Clinical trial with placebo control group with parallel groups, phase 2 double-blind randomized study on 72 patients with simple randomization

Settings and conduct

This study is performed Diabetes Research Center, Endocrinology and Metabolism Research Institute, Tehran University of Medical Sciences, Tehran, Iran. This randomized double blind placebo controlled clinical trial is performed in parallel groups of diabetic patients. Physicians, patients, researchers, and data analyzer are blind to study groups.

Participants/Inclusion and exclusion criteria

Type 2 diabetic patients aged 30-70 years with HbA1c 8-10% are included in the study. People with heart and kidney failure, insulin-treated patients, and pregnant and lactating women are excluded from the study.

Intervention groups

Patients in intervention groups will receive ganoderma capsule (1 gr at morning and 1 gr at night) or placebo with the same feature for 12 weeks.

Main outcome variables

Blood glucose

General information

Reason for update

Acronym

none

IRCT registration information

IRCT registration number: **IRCT20200716048118N1**

Registration date: **2020-11-25, 1399/09/05**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-25, 1399/09/05**

Update count: **0**

Registration date

2020-11-25, 1399/09/05

Registrant information

Name

Fatemeh Bandarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

fbandarian@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Ganoderma lucidum (with usual diabetes medications) on blood glucose control in type 2 diabetic patients: A placebo-controlled double-blind clinical trial

Public title

The effect of Ganoderma on glycemic control in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 Diabetic patients age 30-70 HbA1c 8-10%

Exclusion criteria:

liver failure renal failure pregnant women lactating women insulin therapy

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by using random number table is used for randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

physician is blind about the study group. Patient is blind about the study group. investigator is blind about the study group. data analyzer is blind about the study group. Assignment of patients in treatment and placebo groups is performed by a nurse out of above mentioned groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Endocrinology and Metabolism Research Institute, Tehran University of Medical Sc

Street address

Diabetes Research Center, 5th floor, Diabetes clinic, Cross Heyat Ave., Shahrivar Ave., North Kargar St.,

City

Tehran

Province

Tehran

Postal code

1411716411

Approval date

2020-09-28, 1399/07/07

Ethics committee reference number

IR.TUMS.EMRI.REC.1399.046

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood glucose

Timepoint

Begging and at after 12 weeks of treatment

Method of measurement

Biochemical method and autoanalyser

Secondary outcomes

1

Description

Cholesterol Total

Timepoint

Triglyceride

Method of measurement

Biochemistry- Calorimetry

Intervention groups

1

Description

Intervention group: In this group patients take their oral diabetes medications without any changes and in addition, they receive treatment with ganoderma including one ganoderma capsule (one gram ganoderma) in morning and one in night for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo. In this group patients take their oral diabetes medications without any changes and in addition they receive treatment with placebo including one placebo capsule (one gram placebo) in morning and one in night for 12 weeks.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Diabetes Clinic affiliated to Diabetes Research Center

Full name of responsible person

Fatemeh Bandarian

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Yas Daru

Full name of responsible person

Ensieh Nasli-Esfahani

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yas Daru

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Bandarian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

Not applicable

Title and more details about the data/document

None

When the data will become available and for how long

not known

To whom data/document is available

Principle investigator

Under which criteria data/document could be used

Not defined

From where data/document is obtainable

Diabetes Research Center

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

Per case is decided

Comments