Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Ganoderm 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
Patents in intervention groups will receive ganoderma capsule (1 gr at morning and 1 gr at nigh) 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
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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 Ganoderm 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 Ganoderm 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 centers

1

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 sources

1

Sponsor
Name of organization / entity
Yas Daru
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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
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Other areas of specialty/work
Molecular Medicine
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Person responsible for updating data

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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