Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Effect of herbal antidiabetic capsule on blood sugar control in type 2 diabetic patients

Protocol summary

Summary

The present study aim is to investigate the effects of Capparis spinosa, Rosa canina, Securigera securidaca, Silybum marrianum, Urtica dioica, Trigonella foenum-graecum and Vaccinium arctostaphylos extract mixture on glycemic control in patients with type 2 diabetes. Total 150 type 2 diabetic patients, referring to diabetic clinic Baghiatallah Hospital, aged 40 to 60 years with fasting serum glucose levels between 130 to 160 mg/dL and glycosylated hemoglobin between 7.5 to 8.5 percent will be randomly selected to herbal extract, control and placebo groups. The patients in herbal extract group will be treated with capsule containing 500 mg mixture of Capparis spinosa, Rosa canina, Securigera securidaca, Silybum marrianum, Urtica dioica, Trigonella foenum-graecum and Vaccinium arctostaphylos extract and patients in control group will be treated with capsule containing metformin 250 mg mixed with toast powder 250 mg and placebo group will be treated with capsule containing 500 mg toast powder two times a day for 3 months. The patient's anti-diabetic drugs or other medication will be continued and unchanged during the study. Before and at end of the study the blood biochemical tests, including fasting blood glucose and HbA1c are determined as primary outcomes and cholesterol, triglyceride, LDL, HDL, BUN, creatinine, SGOT, and SGPT are determined as secondary outcomes. All data of patients in herbal extract group are compared to control and placebo groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503071157N10**
Registration date: **2016-05-15, 1395/02/26**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

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Hasan Fallah Huseini
Name of organization / entity
Institute of Medicinal Plants
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Institute of Medicinal Plants

Expected recruitment start date

2016-04-29, 1395/02/10

Expected recruitment end date

2016-07-31, 1395/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of herbal antidiabetic capsule on blood sugar control in type 2 diabetic patients

Public title

Effect of herbal extract mixture on treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Type 2 diabetic patients; aged 40 to 60 years; fasting blood glucose levels from 130 to 160 mg/dL; blood glycosylated hemoglobin levels from 7.5 to 8.5 percent; under oral anti-hyperglycemic drugs therapy taking maximum1000 mg metformin and 10 mg glybencalamid daily. Exclusion criteria: Patients receiving insulin therapy; patients with cardiovascular, renal, hepatic, hematological, hypothyroidism, vertigo and seizure diseases; patients with a history of gallstones or gallbladder surgery; patients under estrogen, steroid, beta-blocker and thiazide therapy; women planning for pregnancy; pregnant women; breast-feeding women.

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In this study 150 patients are randomly divided into herbal drug, placebo and control groups encoded with alphabet A, B,C. Block randomization with a computer generated random numbers table and sequentially numbered containers each representing a block consisting of three patients are used for the treatment assignments. Three different persons generate the random allocation sequence, enroll the participants and assign them to interventions. Care providers, participants and the person evaluating the response to treatments are blind to the interventions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Avicenna Research Institute

Street address
Shahid Beheshti University, Tabnak Street, Shahid Chamran Highway, Evin, Tehran. IRAN

City
Tehran

Postal code
1983963113

Approval date
2015-11-17, 1394/08/26

Ethics committee reference number
IR.ACECR.Avicenna.REC.1394.15

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E10, E14,

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Glucose

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood glucose level will be determined in laboratory by commercial standard kit

2

Description
Glycosylated hemoglobin (HbA1c)

Timepoint
At starting of the study and after 3 months

Method of measurement
HbA1c percent will be determined in laboratory by commercial standard kit

Secondary outcomes

1

Description
Triglyceride

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood triglyceride level will be determined in laboratory by commercial standard kit

2

Description
Cholesterol

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood cholesterol level will be determined in laboratory by commercial standard kit

3

Description
low-density lipoprotein (LDL)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood LDL level will be determined in laboratory by commercial standard kit

4

Description
High-density lipoprotein (HDL)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood HDL level will be determined in laboratory by commercial standard kit

5

Description
Aspartate aminotransferase (AST)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood AST level will be determined in laboratory by commercial standard kit

6

Description
Alanine aminotransferase (ALT)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood ALT level will be determined in laboratory by commercial standard kit

7

Description
Blood urea nitrogen (BUN)
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood BUN level will be determined in laboratory by commercial standard kit

8

Description
Creatinine
Timepoint
At starting of the study and after 3 months
Method of measurement
Blood creatinine level will be determined in laboratory by commercial standard kit

Intervention groups

1

Description
Intervention group: Herbal extract capsule (500 mg) will be administered 2 times a day orally for 3 months. Control group: Metformin capsule (250 mg) mixed with toast powder (250 mg) will be administered 2 times a day orally for 3 months. Placebo group: Placebo capsule (500 mg toast powder) will be administered 2 times a day orally for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghiatallah Hospital
Full name of responsible person
Reza Mohtashami
Street address
Mollasadra Street, Vanak Square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Institute of Medicinal Plants
Full name of responsible person
Reza Hajiaghaee
Street address
Kavosh Boulevard, Supa Boulevard, 55th km of Tehran-Qazvin Highway, Research Complex of Jahad Daneshgahi
City
Karaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Institute of Medicinal Plants
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Institute of Medicinal Plants

Full name of responsible person
Hasan Fallah Huseini

Position
Ph.D. in Pharmacology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty