

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

Name

Hasan Fallah Huseini

Name of organization / entity

Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26 3476 4010

Email address

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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 maximum 1000 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**Street address**

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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