# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Effects of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf mixture on type 2 diabetic patients

## Protocol summary

**Summary**

This project aims to investigate the effect of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf extract mixture on fasting blood glucose and glycosylated hemoglobin in patients with type 2 diabetes. Total 60 type 2 diabetic patients aged 40 to 60 years with fasting serum glucose levels of 150 to 180 mg/dL and glycosylated hemoglobin of 7.5 to 8.5 percent, referring to Diabetic Clinic in Baghiyatallah Hospital will be randomly and equally selected into herbal drug and placebo groups. Herbal drug is mixture of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf extracts and placebo is prepared using toast powder. The patients in herbal group will be taken a Herbal drug capsule three times daily for 3 months and placebo group will be taken placebo capsule in the same manner. The patient antidiabetic drugs or other treatments will be continued and unchanged during the study. Before and at end of the study the blood biochemical tests, including fasting blood glucose and glycosylated hemoglobin are determined as primary outcomes and fasting blood triglycerides, cholesterol, low-density lipoprotein, high-density lipoprotein, aspartate aminotransferase, alanine aminotransferase, creatinine and blood urea nitrogen are determined as secondary outcomes. All data of herbal group are compared to placebo group.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201502011157N9**
Registration date: **2015-03-06, 1393/12/15**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2015-03-06, 1393/12/15

**Registrant information**

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

**Recruitment complete**

**Funding source**

Institute of Medicinal Plants

**Expected recruitment start date**

2015-05-22, 1394/03/01

**Expected recruitment end date**

2016-02-20, 1394/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf mixture on type 2 diabetic patients

**Public title**

To investigate the effect of Olibanum Gum, Silybum marianum seed and Urtica dioica leaf extracts mixture on blood sugar and glycosylated hemoglobin in type 2 diabetic patients: a double blind, randomized, placebo controlled trial.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria:Type 2 diabetic patients; aged 40 to 60 years; fasting blood glucose levels from 150 to 180 mg/dL; blood glycosylated hemoglobin levels from 7.5 to 8.5 percent; under therapy of oral anti-hyperglycemic drugs maximum 10 mg glyburide and 1000 mg metformin daily. Exclusion criteria: Patients receiving insulin therapy; patients with cardiao vascular, renal, hepatic, hematological, hypothyroidism, vertigo and seizure diseases; patients with a history of gallstones or gall bladder surgery; patients under estrogen, steroid, beta-blocker and thiazide therapy; pregnant women; women planning for pregnancy and breast-feeding women.

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

The study will not be conducted in the Ramazan month and Norooz days

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Avicenna Research Institute

**Street address**

Shariati AVE, Yakhchal street, Avicenna Research Institute Central Building

**City**

Tehran

**Postal code**

**Approval date**

2015-02-20, 1393/12/01

**Ethics committee reference number**

Under consideration

## 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**

Fasting blood glucose

**Timepoint**

At starting of the study and after 3 months

**Method of measurement**

Blood glucose level will be determined in laboratory by commercially available 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 commercially available kit

## Secondary outcomes

### 1

**Description**

Cholesterol

**Timepoint**

At starting of the study and after 3 months

**Method of measurement**

Blood cholesterol level will be determined in laboratory by commercially available kit

### 2

**Description**

Triglyceride

**Timepoint**

At starting of the study and after 3 months

**Method of measurement**

Blood triglyceride level will be determined in laboratory by commercially available kit

### 3

**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 commercially available kit

**4**

**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 commercially available kit

**5**

**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 commercially available kit

**6**

**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 commercially available kit

**7**

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

**8**

**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 commercially available kit

## Intervention groups

**1**

**Description**
Herbal Drug: 600 mg 3 times a day after food
**Category**
Treatment - Drugs

**2**

**Description**
Placebo: 600 mg 3 times a day after food
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Baghiatallah Hospital
**Full name of responsible person**
Dr. Reza Mohtashami
**Street address**
Baghiatallah Medical College, 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**
Research Complex of Jahad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55-kilometer of the Tehran-Qazvin Highway
**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**
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Institute of Medicinal Plants

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## Person responsible for updating data

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**Email**
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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*