

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of effect of Terminalia chebula fruit, Commiphora myrrh and Commiphora mukul oleo-gum-resin mixture on glycemic control and lipid profile in type 2 diabetic patients with hyperlipidemia: A double blind, randomized, placebo controlled clinical trial.

Protocol summary

Summary

The present study aim is to investigate the effects Terminalia chebula fruit, Commiphora myrrh and Commiphora mukul oleo-gum-resin mixture on hyperlipidemic type 2 diabetic patients. Total 80 hyperlipidemic type 2 diabetic patients, aged 40 to 60 years with fasting serum glucose levels between 150 to 180 mg/dL and glycosylated hemoglobin between 7.5 to 8.5 percent will be randomly selected to herbal drug and placebo groups. Herbal drug are mixture of T. chebula fruit, C. myrrh and C. mukul oleo-gum-resin and placebo are prepared using toast powder. Herbal drug and placebo are formulated in the form of 600 mg capsules and will be administered to patients three times daily for 3 months. The patients antidiabetic 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, HbA1c, cholesterol, triglyceride, LDL, HDL, BUN, creatinine, SGOT, and SGPT are determined. All data results of herbal group are compared to placebo group

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307011157N8**
Registration date: **2015-03-08, 1393/12/17**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-03-08, 1393/12/17

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

fallah@imp.ac.ir

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

Evaluation of effect of Terminalia chebula fruit, Commiphora myrrh and Commiphora mukul oleo-gum-resin mixture on glycemic control and lipid profile in type 2 diabetic patients with hyperlipidemia: A double blind, randomized, placebo controlled clinical trial.

Public title

Effect of herbal drug Terminalia chebula, Commiphora myrrh and Commiphora mukul mixture on diabetes in patients with hyperlipidemia .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian 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; LDL-c > 100 mg/dL; triglyceride >150 mg/dL; oral intake of not more than 10 mg glyburide and 1000 mg metformin at maximum. Exclusion criteria: Patients receiving insulin therapy; patients with cardiovascular, 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; 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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Research Institute

Street address

Rashidodin Fazlolah Street, Yaman Ave, Shaheed Chamran Highway, Evin

City

Tehran

Postal code

1177-19615

Approval date

2013-05-25, 1392/03/04

Ethics committee reference number

650-15-1392-ص

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10, E14,

ICD-10 code description

Non-insulin-dependent diabetes mellitus

2

Description of health condition studied

Added at 2015-07-20: Mixed hyperlipidaemia

ICD-10 code

Added at 2

ICD-10 code description

Added at 2015-07-20: Hypercholesterolaemia with endogenous hyperglyceridaemia and Hyperlipidaemia, group C

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

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

3

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

4

Description

Alanine transaminase (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

5

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

6

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

7

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

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 commercial standard kit

Intervention groups

1

Description

Intervention group: 600 mg herbal drug capsule is administered 3 times a day orally for 3 months

Category

Treatment - Drugs

2

Description

Placebo group: 600 mg placebo capsule is administered 3 times a day 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

Baghiatallah Hospital, Baghiatallah Medical College, Mollasadra Street, Vanak Squar

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 Jihad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55th km of 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****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**Research Complex of Jihad Daneshgahi, Kavosh
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Postal code**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*