Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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-resinin 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
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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

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 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; 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 after3 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 Jahad 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
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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