Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The efficacy of Rheum ribes L stalk extract on lipid profile in hypercholesterolemic type II diabetic patients a randomized, double-blind, placebo-controlled, clinical trial.

Protocol summary

Summary

The present study was designed to investigate the efficacy of Rheum ribes stalk extract on cholesterol profile in type II diabetic patients suffering from hypercholesterolemia. Total of 36 patients aged between 40 to 60 years with confirmed type II diabetes (fasting blood glucose between 150-250 mg/dl), HbA1c 7.5-10%, hypercholesterolemia (LDL cholesterol above 100 mg/dl) and taking antidiabetic drug, such as Metformin or Glibenclamid, were selected. All the patients signed the written informed consent and were randomly allocated into equal groups of placebo and Rheum Ribes. The patients were not taking any antihyperlipidemic drug during past month and received their standard anti-diabetic therapy without any change during the study. All patients with severe kidney, liver, heart and pulmonary diseases, hypersensitivity to any drug, foot ulcer or gangrene, major depressive disorder, previous myocardial infarction, active cancer or previous cancer during past 5 years, alcohol consumption, cigarette smoking, pregnancy and breast feeding, were excluded. The patients were randomly allocated into one of two groups. One group received 1200 mg Rheum Ribes L, daily in three 400 mg capsules and others received the same capsules as placebo. Fasting blood glucose, total cholesterol, LDL, HDL cholesterol, triglyceride, creatinine, SGOT and SGPT were measured at the beginning and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706111157N1**
Registration date: **2009-04-11, 1388/01/22**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2009-04-11, 1388/01/22

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 Plant ACECR / Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2006-05-21, 1385/02/31

Expected recruitment end date

2007-05-21, 1386/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of Rheum ribes L stalk extract on lipid profile in hypercholesterolemic type II diabetic patients a randomized, double-blind, placebo-controlled, clinical trial.

Public title
The efficacy of Rheum ribes L stalk extract on lipid profile in hypercholesterolemic type II diabetic patients. A randomized, double-blind, placebo-controlled, clinical trial.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age between 40 to 60 years, serum cholesterol above 100 mg/dl, confirmed type II diabetes at least for two years with fasting blood glucose above 150-250 mg/dl taking Metformin or Glibenclamid, HbA1c 7.5-10%, not taking any antihypercholesterolmic drug during past month, signing the written informed consent. Exclusion criteria: Insulin therapy, infectious diseases, severe kidney, liver, heart and pulmonary diseases, hypersensitivity to any drug, foot ulcer or gangrene, major depressive disorder, previous myocardial infarction, active cancer or previous cancer during past 5 years, history of alcohol consumption or cigarette smoking, pregnancy, breast feeding.
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **36**
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
Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences
Street address
Endocrinology & Metabolism Research Center, Tehran University of Medical Sciences Tehran IR IRAN
City
Tehran
Postal code
1484958693
Approval date
2005-11-10, 1384/08/19
Ethics committee reference number
134/ف/ع

Health conditions studied

1

Description of health condition studied
Hypercholesterolemia
ICD-10 code
E78
ICD-10 code description
Disorders of lipoprotein metabolism and other lipidaemias

Primary outcomes

1

Description
LDL cholesterol
Timepoint
Baseline and after one month
Method of measurement
The fasting serum LDL cholesterol concentration determined in blood sample by calculating HDL and total cholesterol level

2

Description
Blood glucose
Timepoint
Baseline and after one month
Method of measurement
The fasting serum glucose concentration determined in blood sample by glucose oxidase method.

Secondary outcomes

1

Description
Total cholesterol
Timepoint
Baseline and after one month
Method of measurement
The fasting serum total cholesterol level in blood sample by enzymatic oxidase method.

2

Description
HDL
Timepoint
Baseline and after one month
Method of measurement
The fasting blood HDL level in blood sample by CDC designated comparison method.

3

Description
Triglyceride
Timepoint
Baseline and after one month
Method of measurement
The fasting blood Triglyceride level in blood sample by enzymatic oxidase method

4

Description
SGOT
Timepoint
Baseline and after one month
Method of measurement
The fasting blood SGOT level in blood sample by DGKG enzymatic method.

5

Description
SGPT
Timepoint
Baseline and after one month
Method of measurement
The fasting blood SGPT level by DGKG enzymatic method

6

Description
Creatinine
Timepoint
Baseline and after one month
Method of measurement
The fasting blood Creatinine level in blood sample by JAPH enzymatic method.

Intervention groups

1

Description
Placebo capsule 400 mg 3 times a day treatment orally for one month
Category
empty

2

Description
Rheum Ribes 400 mg capsule 3 times a day treatments orally for one month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Research Center
Full name of responsible person
Ramin Heshmat
Street address
Shariati Hospital, Tehran University of Medical Sciences
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahad Daneshgahi
Full name of responsible person
Haji Tarverdi
Street address
Jahad Daneshgahi, Engelab St.
City
Tehran
Grant name
ریواس 6/3/1386 -6736/20/28
Grant code / Reference number
1374/23
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahad Daneshgahi
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Endocrinology & Metabolism Research Center
Full name of responsible person
Ramin Heshmat
Street address
Shariati Hospital Tehran University of Medical Sciences Tehran IR. Iran.
City
Tehran
Grant name
ریواس 6736/20/28- 6/3/1386
Grant code / Reference number
1374/23
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Endocrinology & Metabolism Research Center

Proportion provided by this source

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, ACECR

Full name of responsible person

Hassan Fallah Huseini

Position

Ph.D.

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