

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

###### Phone

+98 26 3476 4010

###### Email address

fallah@imp.ac.ir

##### 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 antihypercholesterolemic 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/ع/ف

**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**

6/3/1386 -6736/20/28 ریواس

**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**

6736/20/28- 6/3/1386 ریواس

**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*

karaj  
**Postal code**  
31375369  
**Phone**  
+98 261476401019  
**Fax**  
+98 26 1476 4021  
**Email**  
fallah@imp.ac.ir huseini\_fallah@yahoo.com  
**Web page address**  
www.imp.ac.ir

## 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**  
**Street address**  
Jahad daneshgahi research society, Tehran-Qazvin  
Highway  
**City**  
Karaj  
**Postal code**  
31375369  
**Phone**  
+98 261476401019  
**Fax**  
+98 26 1476 4021  
**Email**  
fallah@imp.ac.ir huseini\_fallah@yahoo.com  
**Web page address**  
www.imp.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Institute of Medicinal Plants, ACECR  
**Full name of responsible person**  
Hassan Fallah Huseini  
**Position**  
PhD  
**Other areas of specialty/work**  
**Street address**  
Jahad daneshgahi research society, Kavosh Research  
Town  
**City**  
karaj  
**Postal code**  
31375369  
**Phone**  
+98 261476401019  
**Fax**  
+98 26 1476 4021  
**Email**  
fallah@imp.ac.ir / huseini\_fallah@yahoo.com  
**Web page address**  
www.imp.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Institute of Medicinal Plants  
**Full name of responsible person**  
Hassan Fallah Huseini  
**Position**  
Ph.d.  
**Other areas of specialty/work**  
**Street address**  
Jahad-Daneshgahi research society (ACECR) Tehran-  
Qazvin Highway,  
**City**

## 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*