# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluating the effect of juglans regial extract on blood glucose and lipid profile in type II diabetic patients

## Protocol summary

**Summary**

The present study was designed to investigate the efficacy of Juglans regial extract dry powder on blood glucose and lipid profile in type II diabetic patients.61 patients aged between 40 to 60 years, fasting blood glucose between 150-250 mg/dl and HbA1c 7.5-10% taking anti diabetic drug such as Metformin or Glibenclamid that signed the written informed consent will be selected. All patients who suffering from severe kidney, liver, heart and pulmonary diseases, hypersensitivity to any drug, foot ulcer or gangrene, active cancer or previous cancer during the last 5 years, alcoholic or cigarette smoker individuals, pregnant and breast feeding patients will be excluded. The patients will be randomly allocated into two groups. One group received 200 mg juglans regia as capsules, two times daily, for 3 month and second group received placebo capsules. Fasting blood glucose, glycosilated hemoglobin, total cholesterol, LDL, HDL cholesterol, triglyceride, creatinine, SGOT and SGPT were measured at the beginning and after three months.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201106076720N1**
Registration date: **2012-03-09, 1390/12/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-03-09, 1390/12/19

**Registrant information**

**Name**

Leila Jamshidi

**Name of organization / entity**

Tehran University of Medical Scienses

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8822 0038

**Email address**

leila_jamshidi4@yahoo.com

**Recruitment status**

**Recruitment complete**

**Funding source**

Institute of Medicinal Plant ACECR, Endocrinology & Metabolism Research Center

**Expected recruitment start date**

2010-10-23, 1389/08/01

**Expected recruitment end date**

2011-05-22, 1390/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the effect of juglans regial extract on blood glucose and lipid profile in type II diabetic patients

**Public title**

Effect of juglans regial on diabetes

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: age between 40 to 60 years; confirmed type II diabetes at least for two years with fasting blood glucose 150-250 mg/dl; taking metformin or glibencalamid; having HbA1c 7.5-10%; All patients singed the written informed consent. Exclusion criteria: insulin therap; infectious diseases; severe kidney disease with Cr>270 umol/L; liver, heart or pulmonary disease;

hypersensitivity to any drug; foot ulcer or gangrene; major depressive disorders; active cancer or previous cancer during the last 5 years; alcohol consumption; cigarette smoking; pregnancy and 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: **61**

**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

**City**
Tehran

**Postal code**
1484958693

**Approval date**
2011-01-23, 1389/11/03

**Ethics committee reference number**
257

## Health conditions studied

### 1

**Description of health condition studied**
Diabetes

**ICD-10 code**
E11

**ICD-10 code description**
Non-insulin-dependent diabetes mellitus

### 2

**Description of health condition studied**
Disorder of lipoprotein metabolism

**ICD-10 code**
E78.9

**ICD-10 code description**
Disorder of lipoprotein metabolism, unspecified

## Primary outcomes

### 1

**Description**
Glycosylated hemoglobin

**Timepoint**
Baseline and after three months

**Method of measurement**
HPLC method

### 2

**Description**
TG - total cholesterole

**Timepoint**
Baseline and after three months

**Method of measurement**
Fasting blood Cholesterol and TG level in Baseline and after three months by enzymatic oxidase method.

### 3

**Description**
Fasting blood glucose

**Timepoint**
Baseline and after three months

**Method of measurement**
Glucose oxidase method

## Secondary outcomes

### 1

**Description**
SGOT

**Timepoint**
Baseline and after three months

**Method of measurement**
SGOT level in fasting blood sample by DGKG enzymatic method

### 2

**Description**
SGPT

**Timepoint**
Baseline and after three months

**Method of measurement**
SGPT level in fasting blood sample by DGKG enzymatic method

**3**

**Description**
Creatinin
**Timepoint**
Baseline and after three months
**Method of measurement**
The fasting blood Creatinin level by JAPH enzymatic method

## Intervention groups

**1**

**Description**
Intervention: Juglans regial extrac powder 200 mg in capsule two times a day for three months
**Category**
Treatment - Drugs

**2**

**Description**
Control: placebo 200 mg in capsule two times a day for three months
**Category**
Placebo

## Recruitment centers

**1**

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

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Jahad Daneshgahii
**Full name of responsible person**
Haji Tarverdi
**Street address**
Jahad Daneshgahii, Engelab Ave
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Jahad Daneshgahii
**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
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**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**
Endocrinology & Metabolism Research Center
**Full name of responsible person**
Leila Jamshidi
**Position**
M.S
**Other areas of specialty/work**
**Street address**
Shariati Hospital, Tehran University of Medical Sciences
**City**
Tehran
**Postal code**
141554364
**Phone**
**Fax**
**Email**

Leila_jamshidi4@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Endocrinology & Metabolism Research Center

**Full name of responsible person**

Leila jamshidi

**Position**

M.S

**Other areas of specialty/work**

**Street address**

Shariati Hospital, Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

141554364

**Phone**

**Fax**

**Email**

Leila_jamshidi4@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Endocrinology & Metabolism Research Center

**Full name of responsible person**

Leila jamshidi

**Position**

M.S

**Other areas of specialty/work**

**Street address**

Shariati Hospital, Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

141554364

**Phone**

**Fax**

**Email**

Leila_jamshidi4@yahoo.com

**Web page address**

## 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*