Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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)

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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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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