Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of hydro alcoholic extract of Juglans regia leaves on blood glucose in adults with type 2 diabetes

Protocol summary

Summary

This double blind clinical trial was designed to evaluate the effect of hydro alcoholic extract of Juglans regia leaves on blood sugar in adults with type 2 diabetes referred to Imam Khomeini hospital, diabetes center in Sari. The study population consist of 40 patients that will be divided into two groups randomly whereas will be matched for age, sex and BMI. One Group will receive 100 mg of prepared powder of drug and other group will receive placebo for 8 weeks. Blood pressure, Fasting blood sugar (FBS), Insulin and HbA1C will be measured at baseline. After 1, 2, 4 and 8 weeks, the patients will be examined by a general physician who is blind to type of treatment. The number of remained drug will be counted and the adverse effects of drug will be recorded. Measurement of FBS will be repeated after 4 and 8 weeks and Insulin, HbA1C after 8 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901203180N2**
Registration date: **2010-06-06, 1389/03/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-06-06, 1389/03/16

Registrant information

Name

Zahra Kashi

Name of organization / entity

Mazandaran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1226 1701

Email address

zkashi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2010-05-01, 1389/02/11

Expected recruitment end date

2011-05-01, 1390/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydro alcoholic extract of Juglans regia leaves on blood glucose in adults with type 2 diabetes

Public title

The effect of hydro alcoholic extract of Juglans regia leaves on blood glucose in adults with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 30 to 80, HbA1C>7% in spite of using 50% of maximal dose of two antidiabetic drug. Exclusions criteria: Immune deficiency, pregnancy and lactation, cardiovascular disease, currently receiving corticosteroids and thiazide, uncontrolled thyroid dysfunction, acute infection ,history of diabetic ketoacidosis , Cr>1.5 for male, Cr>1.2 for female, acute hepatitis, cirrhosis, proliferative retinopathy and severe weight loss (at least 10% during last 6 months)

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethic committee of Mazandaran University of medical sciences

Street address

Imam Sq., Valiye asr highway

City

Sari

Postal code

Approval date

2010-03-03, 1388/12/12

Ethics committee reference number

144-88

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

HbA1C

Timepoint

before and after intervention

Method of measurement

laboratory

2

Description

FBS

Timepoint

before and 4 and 8 weeks after intervention

Method of measurement

laboratory

Secondary outcomes

1

Description

serum insulin

Timepoint

before and 8 weeks after intervention

Method of measurement

laboratory

2

Description

lipid profile

Timepoint

before and 4 and 8 weeks after intervention

Method of measurement

laboratory

3

Description

weight

Timepoint

before and after intervention

Method of measurement

weight Scale

Intervention groups

1

Description

Intervention group: capsule contains 100 mg of hydro alcoholic extract of Juglans regia leaves, twice daily for 8 weeks

Category

Treatment - Drugs

2

Description

Placebo group: flour of bean capsul, twice daily for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes center of Imam Khomeini hospital
Full name of responsible person
Parisa Rabie
Street address
Razi street
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences and Health Services
Full name of responsible person
Dr Ahmad Ali Enaiati
Street address
Deputy of research and technology, Mazandaran university of medical sciences
City
Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran University of Medical Sciences and Health Services
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
Mazandaran University of Medical Sciences and Health Services
Full name of responsible person
Parisa Rabie
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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