

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation the effect of standardized ginseng extract Panax (G115 ®) on blood glucose levels, glycated hemoglobin and lipid profile in patients with diabetes type 2: double blind randomized placebo controlled trial

Protocol summary

Summary

The aim of this study was to investigate the effect of standardized ginseng extract panax (G115) on glucose, glycosylated hemoglobin and lipid profile in patients with diabetes type 2. This study is a double blind randomized placebo controlled trial. Patients who have at least 40 years of age, use oral drug for controlling blood glucose, do not inject insulin and have not an allergy to ginseng will be enrolled randomly in 2 groups: ginseng extract and placebo. Fasting blood glucose, HBA1C, HDL, LDL, VLDL, TG and Cholesterol are measured before and 8 weeks after the intervention. Ginseng extract group will receive 300 mg of standardized ginseng extract three times a day and every time 100 mg, 30 minutes before breakfast, lunch and dinner. Placebo group will receive placebo capsule (1 gr of Wheat flour) in same protocol with the other group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103196090N1**

Registration date: **2012-09-04, 1391/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-04, 1391/06/14

Registrant information

Name

Reza Malihi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1333 3050

Email address

r.malihi@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-04-08, 1391/01/20

Expected recruitment end date

2012-05-04, 1391/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of standardized ginseng extract Panax (G115 ®) on blood glucose levels, glycated hemoglobin and lipid profile in patients with diabetes type 2: double blind randomized placebo controlled trial

Public title

Evaluation the effect of standardized ginseng extract on blood glucose levels and lipid profile in patients with diabetes type 2.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Fasting blood glucose greater than or equal to 126 mg/dL; At least 40 years of age; At least two years of experience of type 2 diabetes; using oral drug for controlling blood glucose (metformin,

glibenclamide); No history of other diseases (such as, cardiovascular, hepatic, renal and metabolic disorders); BMI 25 to 35. Exclusion criteria: Allergies to ginseng extract; ketonuria symptoms; need for insulin.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Blvd

City

Ahvaz

Postal code

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

ETH-491

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Primary outcomes

1

Description

fasting blood glucose

Timepoint

before and after 8 weeks intervention

Method of measurement

mg/dl

2

Description

HBA1C %

Timepoint

before and after 8 weeks intervention

Method of measurement

percent of HBA1C

3

Description

lipid profiles

Timepoint

before and after 8 weeks intervention

Method of measurement

LDL,HDL,Chol,TG,VLDL

Secondary outcomes

1

Description

blood pressure

Timepoint

once every 2 weeks

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

ginseng extract group will receive 300 mg of standardized ginseng extract(G115) three times a day and every time 100 mg , 30 minutes before breakfast , lunch and dinner

Category

Other

2

Description

placebo group will receive placebo(1g Wheat flour) three times a day and every time 100 mg , 30 minutes before breakfast , lunch and dinner

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital Clinic

Full name of responsible person

Dr. Ali Ehsanpour

Street address

Amaniyeh-Razi Hospital Clinic

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feqhi

Street address

Golestan Blvd

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Reza Malihi

Position

student of MSc. of Nutrition

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences ,
Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 1333 3050

Fax

Email

r.malihi@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz jundishapur university of medical sciences

Full name of responsible person

Seyyed Ahmad Hosseini

Position

PhD of Clinical Biochemistry

Other areas of specialty/work

Street address

Ahvaz jundishapur university of medical sciences,
Golestan Blvd

City

Ahvaz

Postal code

Phone

+98 61 1333 3050

Fax

Email

seyyedahmadhosseini@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Reza Malihi

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

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