

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effects of standardized ginseng extract panax (G115 ®) on inflammatory biomarkers and glycated hemoglobin 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 glycosylated hemoglobin and inflammatory biomarkers 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. HBA1C, IL6, hsCRP, TNF 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: **IRCT2013040812949N1**

Registration date: **2013-05-25, 1392/03/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-25, 1392/03/04

Registrant information

Name

Meysam Alipour

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1333 3050

Email address

alipour.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of standardized ginseng extract panax (G115 ®) on inflammatory biomarkers and glycated hemoglobin in patients with diabetes type 2: double blind randomized placebo controlled trial

Public title

Evaluation the effect of standardized ginseng extract on glycated hemoglobin levels and inflammatory biomarkers in patients with diabetes type 2.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age between 40 to 60 years, Minimum 2 years experience in diabetes, Receiving medication to control blood sugar, Blood glucose ≥ 126 mg/dl exclusion criteria: need to injection insulin, smoking, Pregnancy and lactation, Consumption Non-steroidal anti-inflammatory drugs, Diuretics, Corticosteroids

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: **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**

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Avenue. Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2013-02-28, 1391/12/10

Ethics committee reference number

ETH-712

Health conditions studied**1****Description of health condition studied**

diabetes mellitus type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

HBA1C %

Timepoint

before and after 8 weeks intervention

Method of measurement

percent of HBA1C

Secondary outcomes**1****Description**

inflammatory biomarkers

Timepoint

before and after 8 weeks intervention

Method of measurement

IL6,hsCRP,TNF

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**

Golestan Hospital Clinic

Full name of responsible person

Dr. Mehrnoosh Zakerkish

Street address

Golestan- Golestan 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 - Ahvaz Jundishapur University of
Medical Sciences

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

Meysam Alipour

Position

Student of MSc. of Nutrition

Other areas of specialty/work**Street address**

Golestan Blvd, Ahvaz Jundishapur University of
Medical Sciences

City

Ahvaz

Postal code**Phone**

+98 61 1444 6216

Fax**Email**

Alipour.m@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**

Golestan Blvd, Ahvaz Jundishapur University of
Medical Sciences

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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Meysam Alipour

Position

Student of MSc. of Nutrition

Other areas of specialty/work**Street address****City****Postal code****Phone**

00

Fax**Email**

Alipour.m@ajums.ac.ir

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