Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effects of standardized ginseng extract panaxs (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

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour 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 panaxs (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 diabete, Receiving medication to control blood sugar, Blood glucose≥126mg/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 placeb0(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
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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