Clinical Trial Protocol
Iranian Registry of Clinical Trials
29 Apr 2020

Evaluation the effect of standardized ginseng extract Panaxs (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

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 Panaxs (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 %

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
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Reza Malihi
Position
Other areas of specialty/work
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd
City
Ahvaz
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