Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Assessment of the effect of oral hesperidin supplement on glycemic and lipidemic risk factors, visceral adiposity index, serum levels of oxidant, inflammatory and oxidative DNA damage markers in type 2 diabetic patients: A randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Summary

This study aimed to determine the effect of oral hesperidin supplement on glycemic and lipidemic risk factors, visceral adiposity index, serum levels of oxidant, inflammatory and oxidative DNA damage markers in type 2 diabetic patients. In this 2 phase double blind clinical trial 64 patients would be randomly allocated to the supplement or placebo groups using random number tables. neither the patients nor administrator of the treatment know which capsules are being received. All patients will provide 10 ml fasting venous blood samples at the beginning and at the end of the study. Data on dietary, physical activity and anthropometric characteristics and body fat percentage will be recorded. Diabetic Patients will be selected among those who are referred to the Diabetes clinic of Ahvaz Golestan Hospital with at least 3 years history of diabetes and taking oral hypoglycemic agents without a history of heart, liver and kidney disease or other endocrine disorders and will consume 600 milligrams of hesperidin supplement or placebo capsules for 6 weeks and will be followed weekly during the intervention period. body fat percentage, body mass index, glycemic and lipidemic indexes, including fasting glucose, insulin, serum fructosamine, total cholesterol, HDL-C, LDL –C, triglycerid and visceral adiposity index, and serum levels of total antioxidant capacity, malondialdehyde and the inflammatory marker as TNF-α, interleukin-6 (IL-6), hs- CRP and oxidative DNA damage will be detected in all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081810181N6**

Registration date: **2015-10-02, 1394/07/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-10-02, 1394/07/10

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1373 8255

Email address

haidari-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of oral hesperidin supplement

on glycemic and lipidemic risk factors, visceral adiposity index, serum levels of oxidant, inflammatory and oxidative DNA damage markers in type 2 diabetic patients: A randomized, double-blind, placebo-controlled clinical trial

Public title
Effect of oral hesperidin supplementation on glycemic and lipidemicin risk factors and inflammatory and oxidant markers in type 2 diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
inclusion criteria: having type 2 diabetes for at least 3 years, oral hypoglycemic medications consumption and having informed written consent exclusion criteria: any change in type or dose of drug during the last 3 months, BMI ranges above 30, having history of other endocrine disorders, heart, hepatic and kidney diseases,using steroid drugs or hormones, having vitamin or mineral supplementation during previous 3 month
Age
From **25 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
In this double blind study neither the patients nor administering the treatment know which capsules are being received. diabetic patients woul be randomly allocated to the supplement or placebo groups using random number tables.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Golestan Ave. Dept. of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz
City
Ahvaz
Postal code
Approval date
2015-07-25, 1394/05/03
Ethics committee reference number
ir.ajums.rec.1394.254

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E10, E11,
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Viseral Adiposity Index
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
calculating by formula

2

Description
fasting Glucose
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum Glucose concentration in mg/dl by kit

3

Description
Insulin
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum Insulin concentration in µU/ml by kit

4

Description
Serum Fructosamine
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum Fructosamine concentration in µmol/L by kit

5

Description
Serum cholestrol
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting Serum cholestrol concentration in mg/dl by kit

6

Description
HDL Cholestrol
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting Serum HDL Cholestrol concentration in mg/dl by kit

7

Description
LDL Cholestrol
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting Serum HDL Cholestrol concentration in mg/dl, calculating by Friedewald formula

8

Description
Serum Teriglycerid
Timepoint
Baseline, 6 weeks after intervention period
Method of measurement
Fasting serum Teriglycerid concentration in mg/dl by kit

9

Description
TNF-α
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum TNF-α concentration in ng/L by kit

10

Description
IL-6
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum IL-6 concentration in ng/L by kit

11

Description
hs- CRP
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
serum hs- CRP concentration in mg/L by kit

12

Description
Total Antioxidant Capacity
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum Total Antioxidant Capacity in U/ml by kit

13

Description
Serum malondialdehyde
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum malondialdehyde concentration in µmol/ml by kit

14

Description
8OHdG
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
Fasting serum 8OHdG concentration (mg/dl) by kit

Secondary outcomes

1

Description
Body Mass Index
Timepoint
baseline, 6 weeks after intervention period
Method of measurement
body weight / hight square (kg/m2)

Intervention groups

1

Description
oral Hesperidin, 600 mg , one capsule per day for 6 weeks
Category
Treatment - Other

2

Description
oral placebo, 600 mg , one capsule per day for 6 weeks
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center

Golestan Hospital Diabetes Clinic

Full name of responsible person
Mehrnoosh Zakerkish

Street address
Golestan Ave. Diabetes Research Center, Ahvaz Jundishapur University of Medical Science, Ahvaz

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
Ataallah Ghadiri

Street address
Golestan Ave. Vice chancellor for research, Ahvaz Jundishapur University of Medical Science, Ahvaz

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
Dept. of Nutrition, School of Paramedical

Full name of responsible person
Fatemeh Haidari

Position
Associate professor

Other areas of specialty/work

Street address
Golestan Ave. Dept. of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz

City
Ahvaz

Postal code

Phone
+98 61 3373 8330

Fax

Email
haidari58@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Dept. of Nutrition, School of Paramedical

Full name of responsible person
Fatemeh haidari

Position
Associate professor

Other areas of specialty/work

Street address
Golestan Ave. Dept. of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz

City
Ahvaz

Postal code

Phone
+98 61 3373 8330

Fax

Email
haidari58@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Dept. of Nutrition, School of Paramedical

Full name of responsible person
Fatemeh haidari

Position
Associate professor

Other areas of specialty/work

Street address
Golestan Ave. Dept. of Nutrition, School of Paramedical, Ahvaz Jundishapur University of Medical Science, Ahvaz

City
Ahvaz

Postal code

Phone
+98 61 3373 8330

Fax

Email
haidari58@gmail.com

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