

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 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

Registration timing: **registered_while_recruiting**

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.

Last update:

Update count: **0**

Registration date

2015-10-02, 1394/07/10

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

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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015081810181N6**

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

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 lipidemic 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 would 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 $\mu\text{U/ml}$ by kit

4

Description

Serum Fructosamine

Timepoint

baseline, 6 weeks after intervention period

Method of measurement

Fasting serum Fructosamine concentration in $\mu\text{mol/L}$ 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 μ mol/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
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Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences
Full name of responsible person
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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
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Fatemeh Haidari
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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