Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Effect of Supplementation of Hesperidin on Serum Glucose, Insulin, Insulin Resistance, Lipid Profile, Hemoglobin A1C, hs-CRP and IL6 in Type II Diabetic Mellitus Patients

Protocol summary

Summary

This study is a double blind clinical trial to evaluate the effect of supplementation hesperidin serum glucose, insulin, resistance to insulin, hemoglobin A1 C, lipid profile, hs-CRP and IL6 on 48 type II diabetic for 2 months. The patients will be recruited from Institute of Endocrinology and Metabolism, Iran University of Medical Sciences,that the disease has been diagnosed by a doctor. the subjects will be 20-65 y of age. Inclusion criteria are absence of cardiovascular disease, liver disease, kidney disease, inflammation and disease chronic digestive system and will have a BMI of less than 35. Exclusion criteria are، taking insulin, following weigh-reducing diets.The study will be explained to each subject.The subjects were randomly divided into two group recipient supplement hesperidin and contro.The study will be explained to each subject, who signs an informed consent Prior to the study, the subjects will be required to complete 3-days 24-hour dietary recall. Blood samples will be obtained after an overnight fast before and after the study. All anthropometric and physical activity variables will be measured both before and after the trial. Compliance will be assessed from 3-days 24-recalls which obtain at first, in the middle and at the end of the study. Diets and medications dosage will be held constant throughout the study and each subject's exercise level will be kept constant and monitored by physical activity questionnaires (IPAQ).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407242602N12**
Registration date: **2014-08-22, 1393/05/31**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2014-08-22, 1393/05/31

Registrant information

Name
Shahryar Eghtesadi
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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+98 21 8877 9118
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Recruitment status

Recruitment complete

Funding source

Iran University Medical Sciences

Expected recruitment start date

2014-09-10, 1393/06/19

Expected recruitment end date

2014-12-11, 1393/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Supplementation of Hesperidin on Serum Glucose, Insulin, Insulin Resistance, Lipid Profile, Hemoglobin A1C, hs-CRP and IL6 in Type II Diabetic Mellitus Patients

Public title

The effect of hesperidin in the treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being volunteer or Wishing to attend 2.diagnosed with type 2 diabetes for at least 1 year (FPG ≥ 126 mg/dl or 2hPG ≥ 200 mg/dl)3. At least one year history of diabet 4. Not using tobacco 5. Lack of cardiovascular disease, liver disease, kidney disease, chronic inflammatory disease of the gastrointestinal tract 6.HbA1C < 8% 7. 20-65 y old 8. Lack of insulin 9. Not drinking alcohol 10. BMI<35 kg/m2 11. Not using any supplements, antioxidants and vitamins in the last 3 months 12. Not pregnant or nursing 13.TG<400 mg/dl 14. The absence of any skin allergies or digestive antioxidant supplements and vitamins. Exclusion criteria 1.The use of antioxidant supplements and vitamins 2.Use of insulin 3. See allergy symptoms at any time during the study 4.Taking over500ml beverages rich in flavonoids include tea, coffee, citrus juice, which it is determined by taking the 24-hour dietary recalls 5. Accept less than 70 6. Follow weight loss diets 7. NSAID nonsteroidal anti-inflammatory drugs and estrogens, oral contraceptives, anticonvulsants, corticosteroids

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

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

School of Public Health, Iran University of Medical Sciences

Street address

Hemmat Highway, Iran University of Medical Sciences

City

Tehran

Postal code

Approval date

2014-07-14, 1393/04/23

Ethics committee reference number

93/315/637/د

Health conditions studied

1

Description of health condition studied

diabet

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

IL6

Timepoint

After the

Method of measurement

ELISA based on a scale pg / ml

2

Description

hs CRP

Timepoint

After the intervention

Method of measurement

ELISA based on a scale ng / ml

3

Description

glucose

Timepoint

Before the intervention and after the intervention

Method of measurement

Glucose oxidase method based on scale mg / dl

4

Description

insulin

Timepoint

Before the intervention and after the intervention

Method of measurement

ELISA based on a scale µmol / ml

5

Description

Glycated hemoglobin

Timepoint

Before the intervention and after the intervention

Method of measurement

Chromatography based on the percentage of glycated hemoglobin

6

Description
TG
Timepoint
Before the intervention and after the intervention
Method of measurement
By an enzymatic method based on the scale mg / dl

7

Description
TC
Timepoint
Before the intervention and after the intervention
Method of measurement
By an enzymatic method based on the scale mg / dl

8

Description
LDL
Timepoint
Before the intervention and after the intervention
Method of measurement
To help Frydvald formula based on mg / dl

9

Description
HDL
Timepoint
Before the intervention and after the intervention
Method of measurement
By an enzymatic method based on the scale mg / dl

10

Description
Systolic blood pressure
Timepoint
Before the intervention and after the intervention
Method of measurement
Using a pressure gauge based on a scale mm Hg

11

Description
Diastolic blood pressure
Timepoint
Before the intervention and after the intervention
Method of measurement
Using a pressure gauge based on a scale mm Hg

12

Description
Insulin Resistance
Timepoint
Before the intervention and after the intervention
Method of measurement
Using the formula

Secondary outcomes

1

Description
age
Timepoint
Before the intervention and after the intervention
Method of measurement
Using Balance 0/1kg carefully based on kg scale

2

Description
BMI
Timepoint
Before the intervention and after the intervention
Method of measurement
Using the formula

3

Description
physical activity
Timepoint
Before the intervention and after the intervention
Method of measurement
Using a questionnaire, based on three levels of light, medium and heavy

4

Description
Dietary intake
Timepoint
Before the intervention and after the intervention
Method of measurement
based on a 3-day recall measure kcal

5

Description
gender
Timepoint
before the intervention
Method of measurement
Using view on men or women

6

Description
Types of drugs
Timepoint
Before the intervention and after the intervention
Method of measurement
Using a questionnaire based on observation

7

Description
Dose of drugs.

Timepoint
Before the intervention and after the intervention
Method of measurement
Using a questionnaire based on the number of

Intervention groups

1

Description
Hesperidin, Capsules 500 mg, 1 time a day for 2 months
Category
Treatment - Drugs

2

Description
Starch placebo capsules, 500 mg, 1 time a day for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Research Center,Iran University of Medical Sciences
Full name of responsible person
Doctor Iraj. Heydari - Endocrinologist
Street address
Tehran, Taleghani Ave Vldy Street, St. Behafarin
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University Medical Science
Full name of responsible person
Dr Shahryar Eghtesadi
Street address
Hemmat Highway, School of Public Health, Iran University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University Medical Science
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

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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