

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8877 9118

###### Email address

egtesadi@iums.ac.ir

##### 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  $\geq$  126 mg/dl or 2hPG  $\geq$  200 mg/dl)  
3. At least one year history of diabetes  
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/m<sup>2</sup>  
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 over 500ml 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**

93/315/637/5

**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  $\mu$ mol / 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**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University Medical Science

**Full name of responsible person**

Dr Shahryar Egtesadi

**Street address**

Hemmat Highway, School of Public Health, Iran University of Medical Sciences

**City**

Tehran

**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****Contact****Name of organization / entity**

Iran University Medical School

**Full name of responsible person**

Shahryar Egtesadi

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**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*