

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Study of quercetin supplementation on risk factors for cardiovascular disease, inflammatory biomarkers and oxidative stress and the relationship between physical activity level in women with type 2 diabetes

#### Protocol summary

##### Summary

This study investigated the effect of Quercetin supplementation on cardiovascular disease risk factors, inflammatory biomarkers and oxidative stress and correlation with physical activity level in women with type 2 diabetes. This study is a randomized clinical trial On 72 women 55-35 years. daily supplement group receiving One 500 mg capsule quercetin and placebo group receiving An identical placebo capsules for 10 weeks. 10cc blood sample will be collected at the beginning and end of intervention to assess the Indicators related to cardiovascular disease risk factors (Total Cholesterol, LDL-c, HDL-c, triglycerides, blood pressure) Indicators of oxidative stress(TAC,MDA) Inflammatory indices(TNF $\alpha$  , hs-CRP,IL-6) and The glyceimic index(HbA1c. FBS). Food intake assessed by food records in First, the fifth week and The tenth week. .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201011015062N1**  
Registration date: **2011-12-07, 1390/09/16**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-12-07, 1390/09/16

##### Registrant information

##### Name

Reza Ghiasvand

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1792 2742

##### Email address

ghiasvand@hlth.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research Deputy of Isfahan University of Medical Sciences

##### Expected recruitment start date

2011-06-22, 1390/04/01

##### Expected recruitment end date

2011-10-06, 1390/07/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of quercetin supplementation on risk factors for cardiovascular disease, inflammatory biomarkers and oxidative stress and the relationship between physical activity level in women with type 2 diabetes

##### Public title

The effect of quercetin supplementation in women with type 2 diabetes

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria 1. Willingness to participate in the study  
2. Type 2 diabetes diagnosed by a physician 3. Having a

history of diabetes at least 3 years 4. Age between 35-55 years 5. Not smoking and addiction 6. Lack of severe heart disease, stroke, liver disease, renal, gastrointestinal, thyroid, parathyroid, rheumatoid arthritis and infectious disease 7. Lack of insulin 8. Lack of antioxidant supplements in the previous month 9. Lack of pregnancy and lactation Exclusion criteria 1. Need to change the dose and type of drug from the baseline to the end 2. Occurring in pregnancy 3. Less than 70% adherence 4. Unwillingness to continue reading 5. Staying beyond the fixed type and dose of drugs during the intervention. 6. There are diseases that require special treatment

#### Age

From **35 years** old to **55 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **72**

#### 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

Isfahan Regional Bioethics Committie

##### Street address

hezargerib street -Isfahan

##### City

Isfahan

##### Postal code

81745319

#### Approval date

2011-06-20, 1390/03/30

#### Ethics committee reference number

190022

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin dependent type2 diabetes

## Primary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

befor start and end of study

#### Method of measurement

Mercury Barometer - mmHg

### 2

#### Description

total Cholesterol

#### Timepoint

befor start and end of study

#### Method of measurement

Enzymatically-mg/dl

### 3

#### Description

HDL-c

#### Timepoint

befor start and end of study

#### Method of measurement

Enzymatically-mg/dl

### 4

#### Description

LDL-c

#### Timepoint

befor start and end of study

#### Method of measurement

Enzymatically-mg/dl

### 5

#### Description

TG

#### Timepoint

befor start and end of study

#### Method of measurement

Enzymatically-mg/dl

### 6

#### Description

FBS

#### Timepoint

befor start and end of study

#### Method of measurement

Enzymatically-mg/dl

## 7

### **Description**

HbA1c

### **Timepoint**

before start and end of study

### **Method of measurement**

Enzymatically-mg/dl

## 8

### **Description**

MDA

### **Timepoint**

before start and end of study

### **Method of measurement**

ELISA-ng/ml

## 9

### **Description**

total antioxidant capacity

### **Timepoint**

before start and end of study

### **Method of measurement**

Chemical colorimetric-mmol/L

## 10

### **Description**

TNF- $\alpha$

### **Timepoint**

before start and end of study

### **Method of measurement**

ELISA-pg/ml

## 11

### **Description**

hs-CRP

### **Timepoint**

before start and end of study

### **Method of measurement**

ELISA-mg/L

## 12

### **Description**

IL-6

### **Timepoint**

before start and end of study

### **Method of measurement**

ELISA-pg/ml

## 13

### **Description**

diastolic blood pressure

### **Timepoint**

before start and end of study

### **Method of measurement**

Mercury Barometer - mmHg

## Secondary outcomes

### 1

#### **Description**

Physical Activity

#### **Timepoint**

before start and end of study

#### **Method of measurement**

IPAQ Questionnaire-Met.minutes/week

### 2

#### **Description**

Weight

#### **Timepoint**

before start and end of study

#### **Method of measurement**

Weight gauge-Kg

### 3

#### **Description**

food intake

#### **Timepoint**

First, the fifth week, the tenth week

#### **Method of measurement**

Inventory Software N4

### 4

#### **Description**

The waist to hip circumference

#### **Timepoint**

before start and end of study

#### **Method of measurement**

Tape-Centimeter

## Intervention groups

### 1

#### **Description**

The intervention group received daily 500mg capsule quercetin for 10 weeks

#### **Category**

Treatment - Other

### 2

#### **Description**

control group received 500mg placebo(lactose) daily for 10 weeks

#### **Category**

Placebo

## Recruitment centers

### 1

#### **Recruitment center**

**Name of recruitment center**

Research Center for Endocrinology and Metabolism  
**Full name of responsible person**  
**Street address**  
**City**  
Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Research Deputy of Isfahan University of Medical Sciences field  
**Full name of responsible person**  
Peyman Adibi  
**Street address**  
Isfahan University of Medical Sciences, Hezarjarib St., Isfahan  
**City**  
Isfahan

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Research Deputy of Isfahan University of Medical Sciences field

### 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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Isfahan University of Medical Sciences  
**Full name of responsible person**  
Reza Ghasvand  
**Position**  
Ph.D. in Nutritional Sciences  
**Other areas of specialty/work**  
**Street address**  
Isfahan University of Medical Sciences. Hezarjarib St. Isfahan.  
**City**  
Isfahan  
**Postal code**  
**Phone**  
+98 31 1792 2742  
**Fax**  
**Email**  
ghiasvand@hlth.mui.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

## 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*