Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The antioxidant effect of quercetin supplementation on the glycemic control, lipid profile and oxidative stress in type 2 diabetic patients.

Protocol summary

Summary

The purpose of the present study is to evaluate the antioxidant effect of quercetin supplementation on the glycemic control, lipid profile and oxidative stress in type 2 diabetic patients, due to the high prevalence of the disease. In an 8 week single-blind placebo-controlled clinical trial, 44 diabetic patients are randomly assigned into two groups, the interventional (consuming 250-mg quercetin supplement) and the control (consuming cellulose as placebo). Fasting blood samples are taken at the beginning and at week 8 for measuring glucose, insulin, and glycosylated hemoglobin (HbA1C), lipid profile and oxidative stress parameters. Dietary data are also obtained using 24-hour recalls at baseline and at the endpoint of the study. At the end of the study, mean differences of the meseared parameters of the intervention and control groups are analyzed statically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101911168N1**
Registration date: **2013-01-03, 1391/10/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-03, 1391/10/14

Registrant information

Name

Seyedeh Maryam Abdollahzadeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2012-12-05, 1391/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The antioxidant effect of quercetin supplementation on the glycemic control, lipid profile and oxidative stress in type 2 diabetic patients.

Public title

The effects of Quercetin on the management of diabetes mellitus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age range 35-60 years; having controlled diabetes (no need for changes in oral hypoglycemic medication during the study or having HbA1C <7%, pre-prandial capillary blood glucose <150 mg/dl and peak postprandial capillary blood glucose <180 mg/dl); maximum period of 10 years from the diagnosis of the disease; having normal blood pressure (systolic and diastolic blood pressure: <120 mmHg and <80 mmHg, respectively). Exclusion criteria: smoking and/or drinking alcohol; having documented liver/kidney

and/or lung diseases, kidney stone or any other type of chronic and/or acute inflammatory disorder; taking any lipid lowering and/or hypotensive medication and multi-vitamin mineral supplements; having documented clinically significant secondary complication of the disease (i.e. diabetic retinopathy, nephropathy and neuropathy)

Age
From **35 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Iran- Fars- Shiraz- Zand St.-Shiraz University of Medical Sciences

City
Shiraz

Postal code

Approval date
2012-10-07, 1391/07/16

Ethics committee reference number
CT-91-6271

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E10-E14

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
FBS

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement
mg/dl, by using auto-analyzer

2

Description
Insulin

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement
microU/ml, by using an ELISA kit

3

Description
Hb A1C

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement
percentage(%), by using HPLC method

4

Description
Triglyceride

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement
mg/dl, by using auto-analyzer

5

Description
total-cholesterol

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement
mg/dl, by using auto-analyzer

6

Description
LDL-cholesterol

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement
mg/dl, by using auto-analyzer

7

Description
HDL-cholesterol

Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial

Method of measurement

mg/dl, by using auto-analyzer

8

Description
ox-LDL
Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial
Method of measurement
U/L, by using ELISA kit

9

Description
Total Antioxidant Capacity
Timepoint
Baseline and at the endpoint (after 8 weeks) of the trial
Method of measurement
nmol/mL, by using an ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description
Quercetin, an oral 250-mg dietary supplement, once daily, for 8 weeks
Category
Other

2

Description
Acetate cellulose, an oral 250-mg dietary supplement, once daily, for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic, Shiraz
Full name of responsible person
Seyede Maryam Abdollahzadeh
Street address
Nemazee Square, Shiraz, Fars.
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahmeddini
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Shiraz University of Medical Sciences, Zand St., Shiraz, Fars.
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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
Shiraz 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
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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