

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 measured 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)

Phone

+98 71 3649 1126

Email address

abdolahsm@sums.ac.ir

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

Street address

Shiraz University of Medical Sciences, Zand St., Shiraz, Fars.

City

Shiraz

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

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyedeh Maryam Abdollahzadeh

Position

MSc Student in Nutrition

Other areas of specialty/work

Street address

School of Health and Nutrition, Shiraz University of Medical Sciences, Shiraz, Fars.

City

Shiraz

Postal code

71645111

Phone

+98 71 1725 7288

Fax

+98 71 1726 0225

Email

abdolahsm@sums.ac.ir, maryamabdh@gmail.com, maryamabdh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Zohreh Mazloom

Position

Associated Professor in Nutrition

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences, Zand St.,
Shiraz, Fars.

City

Shiraz

Postal code

71645111

Phone

+98 71 1725 7288

Fax

+98 71 1726 0225

Email

zohreh.mazloom@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyedeh Maryam Abdollahzadeh

Position

MSc Student in Nutrition

Other areas of specialty/work

Street address

School of Health and Nutrition, Shiraz University of

Medical Sciences, Shiraz, Fars

City

Shiraz

Postal code

71645111

Phone

+98 71 1725 7288

Fax

Email

abdolahsm@sums.ac.ir, maryamabdh@gmail.com,
maryamabdh@yahoo.com

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