Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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(TNFα , hs-CRP,IL-6) and The glycemic 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)

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+98 31 1792 2742

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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
befor start and end of study
Method of measurement
Enzymatically-mg/dl

8

Description
MDA
Timepoint
befor start and end of study
Method of measurement
ELISA-ng/ml

9

Description
total antioxidant capacity
Timepoint
befor start and end of study
Method of measurement
Chemical colorimetric-mmol/L

10

Description
TNF-α
Timepoint
befor start and end of study
Method of measurement
ELISA-pg/ml

11

Description
hs-CRP
Timepoint
befor start and end of study
Method of measurement
ELISA-mg/L

12

Description
IL-6
Timepoint
befor start and end of study
Method of measurement
ELISA-pg/ml

13

Description
diastolic blood pressure
Timepoint
befor start and end of study
Method of measurement
Mercury Barometer - mmHg

Secondary outcomes

1

Description
Physical Activity
Timepoint
before start and end of sudy
Method of measurement
IPAQ Questionnaire-Met.minutes/week

2

Description
Weight
Timepoint
before start and end of sudy
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 sudy
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 Ghiasvand

Position

Ph.D. in Nutritional Sciences

Other areas of specialty/work

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Email

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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