

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Quercetin on plasma total antioxidant capacity, lipid peroxidation, blood pressure, inflammatory markers and disease activity in patients with Rheumatoid Arthritis

Protocol summary

Summary

The present study is a double-blind, placebo-controlled, randomized trial to investigate the effect of Quercetin on plasma total antioxidant capacity, Malondialdehyde and oxidized- LDL, blood pressure, inflammatory factors and disease activity in patients with Rheumatoid Arthritis. Fifty Rheumatoid Arthritis patients will be recruited and randomly assigned to receive either Quercetin, 500 mg in the form of capsules, or placebo for 8 weeks. Plasma level of MDA, ox-LDL, systolic & diastolic pressure, TAC, hs-CRP, hs-TNF α , disease activity score, physician global assessment, morning stiffness, ESR, RF, assessment of pain by VAS and in order to controlling the confounding factors, weight, height, BMI, 24-h dietary recall, disease duration and severity, drugs type and dosage, physical activity will be measured at the baseline and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807252394N2**

Registration date: **2010-03-13, 1388/12/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-03-13, 1388/12/22

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Iran University of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Quercetin on plasma total antioxidant capacity, lipid peroxidation, blood pressure, inflammatory markers and disease activity in patients with Rheumatoid Arthritis

Public title

Effects of Quercetin on plasma total antioxidant capacity, lipid peroxidation, blood pressure, inflammatory markers and disease activity in patients with Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate in study, Clinical diagnosis of AR (meeting the American college of rheumatology 1987 criteria), Ages between 19 - 70 years , No smoking or addiction , No drug type and dose fluctuation since 1 month prior to the study and during

intervention period , Not having severe cardiovascular, hepatic, kidney, gastrointestinal, thyroid, parathyroid diseases, diabetes and inflammation, Not using medications except for AR conventional drugs, Not using antioxidant supplements during last month, No pregnancy or lactation Exclusion criteria: Compliance less than 70%, Disinclination to continue for cooperation, developing illnesses which need particular cures or interfere with intervention such as increasing the disease activity or trauma

Age

From **19 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Ethics committee of school of health, Iran university of medical sciences

Street address

school of Health, Arjantin Square, Alvand Ave., Tehran

City

Tehran

Postal code

1516846514

Approval date

empty

Ethics committee reference number

3248

Health conditions studied**1****Description of health condition studied**

Rheumatoid Arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

2**Description of health condition studied**

Rheumatoid arthritis

ICD-10 code

M06

ICD-10 code description

Other rheumatoid arthritis

Primary outcomes**1****Description**

total antioxidant capacity (TAC)

Timepoint

8 weeks

Method of measurement

colorimetric assay

2**Description**

hs-TNF-alpha

Timepoint

8 weeks

Method of measurement

ELISA

3**Description**

hs- CRP

Timepoint

8 weeks

Method of measurement

ELISA

4**Description**

ox-LDL

Timepoint

8 weeks

Method of measurement

ELISA

5**Description**

Malondialdehyde

Timepoint

8 weeks

Method of measurement

chemical colorimetric

6

Description

disease activity score- 28 joints(DAS-28)

Timepoint

8 weeks

Method of measurement

Physical examination

7

Description

morning stiffness

Timepoint

8 weeks

Method of measurement

question

8

Description

blood pressure

Timepoint

8 weeks

Method of measurement

sphyngomanometer

Secondary outcomes

1

Description

rheumatoid factor(RF)

Timepoint

8 weeks

Method of measurement

turbidometric assay

2

Description

eritrocyte sedimentation rate(ESR)

Timepoint

8 weeks

Method of measurement

Intervention groups

1

Description

Quercetin supplement, 500 mg caps per day for 8 weeks

Category

Treatment - Drugs

2

Description

placebo caps for 8 weeks

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

rheumatology clinic of Firuzgar hospital

Full name of responsible person

Dr. Mojdeh Zabihi

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

rheumatology clinic of Loghman hospital

Full name of responsible person

Dr. Arman Ahmadzadeh

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran Univesity of Medical Sciences

Full name of responsible person

Dr Mohsen Asadi Lari

Street address

Iran University of Medical Sciences, Hematt express way, Tehran ,Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran Univesity 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Health, Iran University of Medical Sciences

Full name of responsible person

Dr. Shima Jazayeri

Position

Assistant Professor

Other areas of specialty/work**Street address**

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s.jazayeri@iums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Health, Iran University of Medical Sciences

Full name of responsible person

Dr. Shima Jazayeri

Position

Assistant Professor

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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