

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of coenzyme Q10 and placebo on clinical sings, inflammatory factors, matrix metalloproteinases and oxidative status in rheumatoid arthritis patients

Protocol summary

Summary

The purpose of this randomized controlled trial is to investigate the effect of coenzyme Q10 (Co Q10) supplementation on clinical sings, inflammatory factors, matrix metalloproteinases and oxidative status in rheumatoid arthritis patients. According to the American College of Rheumatology criteria, 50 patients with moderate and severe disease who treat with fixed doses of Disease Modifying Anti-Rheumatic Drugs will be included. Patients who are taking antioxidants or omega 3 fatty acids supplements and have liver disease, kidney disease and diabetes should be excluded. Patients will be assigned to intervention or control group via randomized blocks. 25 patients in intervention group will consume daily a 100 mg-capsul of Coenzyme Q 10 and 25 patients in control group will consume placebo for two months. Demographic data will be collected at baseline. Patients will be asked to complete food record questionnaires for three days in the first week and three days in the last week of the study to assess food intakes. Before and after intervention, Disease Activity Score and Health Assessment Questionnaire will be completed for each patient. At the beginning and end of the study 7 ml of venous blood will be taken from patients after 12 hours of fasting to measure the serum levels of interleukin-6, tumor necrosis factor-alpha, matrix metalloproteinase 1, matrix metalloproteinase 3, total antioxidant capacity and malondialdehyde.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311014105N16**
Registration date: **2013-12-16, 1392/09/25**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-16, 1392/09/25

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-21, 1392/09/30

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of coenzyme Q10 and placebo on clinical sings, inflammatory factors, matrix metalloproteinases and oxidative status in rheumatoid arthritis patients

Public title

Effect of CoQ10 on rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Disease diagnosis based on ACR criteria by expert; Fixed type and dose of drugs one month before intervention to the end of the study; Under treatment with DMARDs (Hydroxychloroquine, Prednisone, Methotrexate, Sulfasalazine, and ...); Patients with moderate and severe disease; Catching RA disease at least six months ago; Age between 18 to 65 years; Consent to participate in the study Exclusion criteria: Simultaneously participate in trials of other investigators; Pregnancy or the decision to become pregnant during the study period; Breastfeeding; Taking contraceptive drugs; Consumption of antioxidant supplements (A, C, E); Consumption of omega-3 fatty acids; Having liver, kidney, thyroid, diabetes, or infectious disease; Taking anticoagulants such as warfarin; Smoking or repeated exposure to smoking; Drug addiction; Not wanting to continue; Less than 70% adherence

Age

From **18 years** old to **65 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

In this study, patients and researcher are unaware of the kind of intervention (coenzyme Q10 or placebo) in groups.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht street,

Tabriz

City

Tabriz

Postal code**Approval date**

2013-10-21, 1392/07/29

Ethics committee reference number

92113

2**Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Emergency Alley, Resalat Boulevard, Orumieh

City

Orumieh

Postal code**Approval date**

2013-11-05, 1392/08/14

Ethics committee reference number

umsu.rec.1392.152

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

3**Description of health condition studied**

Rheumatoid Arthritis

ICD-10 code

M08

ICD-10 code description

Juvenile arthritis

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

Malondialdehyde (MDA)

Timepoint

At baseline and 2 months after intervention

Method of measurement

Spectrophotometry

2

Description

Matrix metalloproteinase 1 (MMP-1)

Timepoint

At baseline and 2 months after intervention

Method of measurement

MMP-1 kit

3

Description

Matrix metalloproteinase 3 (MMP-3)

Timepoint

At baseline and 2 months after intervention

Method of measurement

MMP-3 kit

4

Description

Total antioxidant capacity (TAC)

Timepoint

At baseline and 2 months after intervention

Method of measurement

TAC kit

5

Description

Interleukin 6 (IL-6)

Timepoint

At baseline and 2 months after intervention

Method of measurement

IL-6 kit

6

Description

Tumor necrosis factor alpha (TNF- α)

Timepoint

At baseline and 2 months after intervention

Method of measurement

TNF- α kit

7

Description

Health status

Timepoint

At baseline and 2 months after intervention

Method of measurement

Questionnaire

8

Description

Disease activity

Timepoint

At baseline and 2 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

High density lipoprotein (HDL)

Timepoint

At baseline and 2 months after intervention

Method of measurement

HDL kit

2

Description

Triglyceride (TG)

Timepoint

At baseline and 2 months after intervention

Method of measurement

TG kit

3

Description

Cholesterol

Timepoint

At baseline and 2 months after intervention

Method of measurement

Cholesterol kit

4

Description

Low density lipoprotein (LDL)

Timepoint

At baseline and 2 months after intervention

Method of measurement

Calculate with the friedewald equation

5

Description

Body mass index (BMI)

Timepoint

At baseline and 2 months after intervention

Method of measurement

Calculation

Intervention groups

1

Description

Patients in intervention group will receive daily one 100 mg capsule of Coenzyme Q10 with meal for two months

Category

Treatment - Drugs

2

Description

Patients in control group will receive daily one capsule of placebo with meal for two months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Mir Amir Aghdashi

Street address

Imam Khomeini Hospital, Ershad Boulevard, Modarres Boulevard, Orumieh

City

Orumieh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammad Reza Rashidi

Street address

Tabriz University of Medical Sciences, Golgasht Street, Azadi Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Beit Allah Alipour

Position

Associate Professor in Nutrition Sciences

Other areas of specialty/work

Street address

Department of Nutrition, Attar Neishaboori Street, Golgasht Street, Tabriz

City

Tabriz

Postal code

5166614711

Phone

+98 41 1335 7580

Fax

Email

alipourb@tbzmed.ac.ir; balipoor@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hadi Abdollahzad

Position

Ph.D student in Nutrition Sciences

Other areas of specialty/work

Street address

Department of Nutrition, Attar Neishabouri Street, Golgasht Street, Tabriz

City

Tabriz

Postal code

5166614711

Phone

+98 41 1335 7580

Fax

+98 41 1334 0634

Email

hadi_nut@yahoo.com; abdollahzad@kums.ac.ir

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