Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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
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Dr Beit Allah Alipour
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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