Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Effects of oral alpha-lipoic acid supplement on some blood biochemical parameters and clinical status in women with rheumatoid arthritis.

Protocol summary

Summary

In this double blind randomized controlled trial the effects of alpha-lipoic acid supplement on some biochemical markers and clinical status in rheumatoid arthritis patients will be evaluated. Women with RA who are at 20-50 years of age and meet the inclusion criteria will be recruited from clinics of Tabriz University of Medical Sciences. After describing the research, if patients want to attend in our study, an informed written consent will be taken. Eventually, 70 patients will be entered the study and they will be allocated randomly into intervention or placebo group to receive alpha-lipoic acid or maltodextrin (each group receives 2 capsules a day for 8 weeks and each capsule contains 600 mg alpha-lipoic acid or maltodextrin). At the beginning of the study an interviewer fill in a demographic questionnaire (including information about age, job, disease history, etc). Before and after the intervention, anthropometric measurements (BMI, waist and hip circumferences) and disease activity score-28 will be evaluated. At baseline and final, fasting blood samples will be gathered to test hsCRP, TNFa,IL-6, RF ,MMP-3, ICAM-1, VCAM-1, lipid profile (TC, TG, HDL -C and LDL-C), TAC, MDA and arylesterase activity in serum as well as SOD and GSH-Px activities in whole blood. Also, 3-day dietary records, physical activity level and anxiety status will be assessed by special questionnaires before and after the study. Finally, biochemical, clinical, anthropometric and dietary data will be statistically analyzed

General information

Acronym

RA

IRCT registration information

IRCT registration number: **IRCT201205263140N5**
Registration date: **2012-07-22, 1391/05/01**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-07-22, 1391/05/01

Registrant information

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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Tabriz University of Medical Sciences & Nutrition Research center of Tabriz University of Medical Sciences

Expected recruitment start date

2012-07-20, 1391/04/30

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral alpha-lipoic acid supplement on some blood biochemical parameters and clinical status in women with rheumatoid arthritis.

Public title

Effect of alpha-lipoic acid supplement in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female rheumatoid arthritis patients who have ACR criteria 1987 for RA; Age range of 20 to 50 years; disease activity score-28< 5.1; not changing the treatment protocol since 2 months before the study, not receiving antioxidant or anti inflammatory supplements since 1 month before the study; desire to attend in study and signing the informed consent form. Exclusion criteria: pregnancy; lactation; post menopause; receiving hormone replacement therapy; receiving oral contraceptive pill; smoking or being a passive smoker; presence of cancer; diabetes mellitus; hormonal dysfunctions; under nutrition; severe obesity (BMI>40), uncontrolled hypertension; renal failure and hepatic diseases; digestive disorders; other autoimmune and/or inflammatory disease; changing treatment protocol and lifestyle during the study; receiving antioxidant or anti-inflammatory supplements during the study; acceptance rate<75% and unwillingness to continue the study.

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 Tabriz university of medical sciences

Street address

Vice-chancellor for Research, central building, number 2, Tabriz university of medical sciences, Golgasht street

City

Tabriz

Postal code

Approval date

2012-06-12, 1391/03/23

Ethics committee reference number

9153

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Clinical Outcomes

Timepoint

before and after intervention (8 weeks)

Method of measurement

by means of DAS-28 validated questionnaire

2

Description

serum levels of inflammatory factors (IL-6, hsCRP, TNFa)

Timepoint

before and after intervention (60 days)

Method of measurement

by means of special kits in Tabriz Pharmaceutical Research Center

3

Description

Serum level of matrix metalloproteinase-3 (MMP-3)

Timepoint

before and after intervention (60 days)

Method of measurement

by means of special kit in Tabriz Pharmaceutical Research Center

4

Description

serum level of RF (Rheumatoid Factor)

Timepoint

before and after intervention (60 days)

Method of measurement

by means of special kit in Tabriz Pharmaceutical Research Center

5

Description

Serum levels of adhesion molecules: inter cellular adhesion molecule-1 (ICAM-1)and vascular cell adhesion molecule-1 (VCAM-1)

Timepoint

Added at 2015-04-04: Before and after intervention (60 days)

Method of measurement

Added at 2015-04-04: Using commercially available kits and ELISA method

6

Description

Added at 2015-04-29:levels of total antioxidant capacity (TAC), malondialdehyde (MDA)and arylesterase (ARE) activity in serum and superoxide dismutase (SOD)and glutathione peroxidase (GSH-Px) in whole blood

Timepoint

Added at 2015-04-29: Before and after intervention (60 days)

Method of measurement

Added at 2015-04-29: TAC,SOD and GSH-Px will be measured using the spectrophotometric method by commercially available kits. MDA and ARE activity will be measured using the spectrophotometric method by chemical substances (thiobarbituric and phenylacetate respectively

Secondary outcomes

1

Description

Dietary Intake of Energy, Nutrients

Timepoint

before and at the middle of the intervention

Method of measurement

dietary record for 3 days

2

Description

anthropometric parameters (BMI, height, weight, waist circumference, hip circumference)

Timepoint

before and after intervention (60 days)

Method of measurement

Body weight without shoes with calibrated scale, Standing height without shoes, waist and hip circumferences are measured. BMI is calculated with this equation: W(kg) /H(m)2

3

Description

systolic and diastolic blood pressure

Timepoint

before and after 8 weeks intervention

Method of measurement

by means of Mercury barometer

Intervention groups

1

Description

intervantion group: alpha-lipoic acid 2 capsules per day- each capsule containing 600 mg alpha-lipoic acid - 0.5 hour before breakfast and dinner (every 12 hours)- for 8 weeks

Category

Treatment - Drugs

2

Description

control group: maltodextrin 2 capsules per day- each capsule containing 600 mg maltodextrin - 0.5 hour before breakfast and dinner (every 12 hours)- for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golgasht clinic

Full name of responsible person

Dr. Susan Kolahi

Street address

Golgasht clinic, Third Floor, close to Golgasht avenue, Azadi avenue

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice-chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Reza Rashidi

Street address

Vice chancellor for Research, No 2, Central Building, Tabriz University of Medical Sciences, Daneshgah street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice-chancellor of Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor
Name of organization / entity
Nutrition Research center of Tabriz University of Medical Science
Full name of responsible person
Dr. Ali-Reza Ostadrahimi
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Nutrition Research center of Tabriz University of Medical Science, Health and nutrition faculty, Attar Neishabouri Avenue, Golgasht street
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition Research center of Tabriz University of Medical Science
Proportion provided by this source
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

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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