

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Combined Antioxidant Supplementation on Blood Antioxidants indices, Lipid Peroxidation, Lipid Profile and Clinical Outcomes in Female Patients with Rheumatoid Arthritis

Protocol summary

Summary

The aim of this study is to investigate the effect of combined antioxidant supplement on blood antioxidant levels, lipid peroxidation and clinical outcomes in female RA patients. The design of this study is uncontrolled before after study. The population of the study is 40 female with Rheumatoid Arthritis with ages between 40-60 years, having ACR criteria for RA, with constant treatment and drug therapy since 2 months ago, without diabetes mellitus, renal or hepatic disorders, Cushing syndrome who they do not smoke and not to expose with smokers daily at home and they should not take antioxidant supplements. The intervention will include taking one Selenplus capsule (Euro vital company, Germany) contains Selenium 50 mcg, Zinc 8 mg, Vitamin A 400 mcg, Vitamin C 125 mg, and Vitamin E 40mg daily for 3 months. The outcomes will be blood antioxidant indices, lipid profile, lipid peroxidation, serum arylesterase, clinical outcomes, dietary intake of energy and nutrients, weight, and body mass index and emotional stress level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901183655N1**
Registration date: **2010-06-22, 1389/04/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-22, 1389/04/01

Registrant information

Name

Seyed Rafi Arefhosseini

Name of organization / entity

Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice- Chancellor of Nutrition and Health Faculty in Tabriz University of Medical Sciences- Rheumatology Research Team of Medicine Faculty of Tabriz University of Medical Sciences

Expected recruitment start date

2010-06-22, 1389/04/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Combined Antioxidant Supplementation on Blood Antioxidants indices, Lipid Peroxidation, Lipid Profile and Clinical Outcomes in Female Patients with Rheumatoid Arthritis

Public title

The Effect of Selenplus on Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female rheumatoid arthritis patients who have ACR criteria 1987 for RA, age 40-60 yrs old, not changing the treatment protocol since 2 months prior to the study, mild to moderate disease severity,
Exclusion criteria: Presence of diabetes mellitus, hypertension, thyroid dysfunction, renal diseases, hepatic disorders, or Cushing's syndrome, smoking or exposure to passive smoking, changing treatment and drugs, receiving antioxidant supplements

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In the design of this study, confounding factors such as: dietary intake of foods and nutrients, body mass index and emotional stress level will be measured before and after the antioxidant intervention for adjusting the relationship of these variables with study outcomes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Vice- Chancellor of Tabriz University of Medical Sciences

Street address

Research Vice- Chancellor of Tabriz University of Medical sciences, Attar-e-Neishabori avenue, Golgasht avenue, Tabriz

City

Tabriz

Postal code

Approval date

2010-07-06, 1389/04/15

Ethics committee reference number

8912

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

Blood Antioxidant Indices

Timepoint

twice: before and after 3 months

Method of measurement

all of parameters(superoxide dismutase, glutathione peroxidase, catalase, Total antioxidant capacity) by means of enzymatic kits except for catalase(with chemical substances) in Tabriz Pharmaceutical Research Center

2

Description

Clinical Outcomes

Timepoint

twice: before and after 3 months

Method of measurement

by means of DAS-28 validated questionnaire

3

Description

Lipid Profile

Timepoint

twice: before and after 3 months

Method of measurement

all parameters as HDL-C- Total cholesterol- triglyceride with enzymatic kits except LDL-c (by means of Friedwald formula)

4

Description

Lipid Peroxidation

Timepoint

twice: before and after 3 months

Method of measurement

by chemical substances in Tabriz Pharmaceutical Research Center

5

Description

Serum Arylesterase Enzyme

Timepoint

twice: before and after 3 months

Method of measurement

by chemical substances in Tabriz Pharmaceutical Research Center

Secondary outcomes

1

Description

Emotional Stress Level

Timepoint

twice: before and after 3 months

Method of measurement

by validated emotional stress questionnaire- assisted by MSc psychology practioner

2

Description

Dietary Intake of Energy, Nutrients and Comparison with RDA

Timepoint

twice: before and after 3 months

Method of measurement

by validated dietary questionnaires: FFQ and 24- hr recall questionnaire for 3 days- calculated by Nutritionist 3 software

3

Description

weight

Timepoint

twice: before and after 3 months

Method of measurement

weighed by digital scales with 0.1 kg sensitivity

4

Description

Body Mass Index (BMI)

Timepoint

twice: before and after 3 months

Method of measurement

calculated with Quetlet's formula($\text{weight(kg)} / (\text{height}^2(\text{m}))$)

Intervention groups

1

Description

Selenplus capsule(Eurovital company of Germany):
Selenium 50mcg, Zinc 8mg, Vitamin A 400mcg, Vitamin C125mg, Vitamin E 40mg daily for 3 month duration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh Al Raees Clinic of Tabriz

Full name of responsible person

Dr Sousan Kolahi

Street address

Azadi avenue, close to Golgasht avenue, Tabriz

City

Tabriz

2

Recruitment center

Name of recruitment center

Clinic of Tabriz, Sina Hospital

Full name of responsible person

Dr Sousan Kolahi

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close to Maralan square, Azadi avenue, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice- Chancellor of Nutrition and Health Faculty in Tabriz University of Medical Sciences

Full name of responsible person

Dr Bahram Pourghasem Gargari

Street address

Nutrition and Health Faculty, Attar avenue, Golgasht avenue, Tabriz

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 Nutrition and Health Faculty in 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

Rheumatology Research, Faculty of Medicine, Tabriz University of Medical Sciences

Full name of responsible person

Dr Alireza Khabbazi

Street address

Imam Reza Hospital, Attar -e- Neishabori avenue,
Golgasht avenue, Tabriz

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rheumatology Research, Faculty of Medicine, 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

Person responsible for general inquiries

Contact

Name of organization / entity

Nutrition and Health Faculty in Tabriz University of
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Full name of responsible person

Dr Seyed Rafi Arefhosseini

Position

PHD of nutritional biochemistry, Assistant Professor of
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Other areas of specialty/work

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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