

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of combinant antioxidant supplementation on blood ADMA and VEGF levels and clinical outcomes in patient with rheumatoid arthritis

Protocol summary

Summary

The goal of this study is to evaluate the effect of combination antioxidant supplementation on blood ADMA and VEGF levels and clinical outcomes in patient with rheumatoid arthritis. This study is single bind. Sample size is 40. All subjects before the intervention being examined for their disease activity (DAS. After 3 months subjects will be examined and assess DAS to determine the intervention effect. An exclusion criterion is changing method of treatment. Before starting the study, blood samples were taken from all participants after 12-8 h fasting and approximately 5 ml of venous blood was obtained. After the intervention period (3 months) patient's blood samples will be taken again. Patients' blood, VEGF, ADMA with rheumatoid arthritis is to measure to determine the possible effect of interventions on blood VEGF, ADMA.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203116934N2**

Registration date: **2012-05-30, 1391/03/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-05-30, 1391/03/10

Registrant information

Name

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Name of organization / entity

Tabriz Medical Science University

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Recruitment status

Recruitment complete

Funding source

Pharmaceutical research center, Tabriz University of Medical Sciences

Expected recruitment start date

2012-06-20, 1391/03/31

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combinant antioxidant supplementation on blood ADMA and VEGF levels and clinical outcomes in patient with rheumatoid arthritis

Public title

The effect of combinant antioxidant supplementation on blood in patient with rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

People with diagnosis of Rheumatoid arthritis disease according to American College of Rheumatology criteria (ACR) is confirmed. The doctor diagnosed according to criteria ACR (at least 4 criteria for six weeks : 1 - morning stiffness in the joint for at least an hour or more 2 - articular arthritis in three areas or more 4: hand joint arthritis 5- symmetrical arthritis 5 - rheumatoid nodules 6 - positive rheumatoid factor 7 - typical radiographic changes in the wrist and hand) in adult patients with

rheumatoid arthritis and patients visiting the doctor, at least for the past two months have not had a treatment change. Selected at random from among eligible women 30 -60 years old admitted with mild to moderate range of severity of illness would be a specialist; if DAS (Disease Activity Score) below 3/2 is a mild disease and the DAS (Disease Activity Score) is between 3/2-5/1, moderate severity is defined .

Age

From **30 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Tabriz University of Medical Sciences Building, 3rd Floor Research

City

Tabriz

Postal code

Approval date

2011-10-28, 1390/08/06

Ethics committee reference number

921

Health conditions studied

1

Description of health condition studied

Rhumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

Primary outcomes

1

Description

Determine and compare the clinical improvement in patients with rheumatoid arthritis before and after intervention

Timepoint

Before and 3 month after intervention

Method of measurement

DAS questionnaire

2

Description

ADMA concentrations in the serum of patients with rheumatoid arthritis before and three months after the administration of antioxidants

Timepoint

Previous intervention three months after the intervention began

Method of measurement

ELISA method

3

Description

Determine changes in serum VEGF rheumatoid arthritis before and three months after the administration of antioxidants

Timepoint

Before and 3 month after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Investigate the effects of antioxidant drugs

Timepoint

Before and three months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

A tablet supplementation antioxidant compounds, including supplementation with a combination of selenium, zinc, vitamin A, E and C to form oral supplement "Celine Plus" is the order of 50 mg, 8 mg, 400 mg, 40 mg and 125 mg are. will be given to patients after Q Miran disease activity ADMA, VEGF was measured before and after study

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Specialized medical clinics

Full name of responsible person

Susan Kolahi

Street address**City**

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Pharmaceutical research center, Tabriz University of Medical Sciences

Full name of responsible person

Babayi hossein

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Pashmine bulding , Daneshgah avenue

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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

Pharmaceutical research center, 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****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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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