

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of sesamin supplementation on the serum levels of some proteolytic enzymes inflammatory , oxidative stress , cyclooxygenase 2 and lipid profile in rheumatoid arthritis women- triple blind Clinical trial

Protocol summary

Summary

Objectives : Effect of sesamin supplementation on the serum levels of some proteolytic enzymes inflammatory , oxidative stress , cyclooxygenase 2 and lipid profile in rheumatoid arthritis Design :triple blind Clinical trial Procedure:44 patients with rheumatoid arthritis enrolled and the will be divided randomly into two groups and placebo . Inclusion criteria : diagnosis of rheumatoid arthritis specialist according 1987 ACR (ACR); Lack of pregnancy and lactation Exclusion criteria : diseases that require special treatment and the intervention disrupts (such as accidents , trauma or exacerbation for reasons such as extreme stress); alcoholic ; allergic to sesame Intervention: the intervention group Will receive sesamin 200 mg capsule daily or a placebo for 6 weeks will be used by other groups . The main outcome variables : indicators of disease activity (DAS-28), total antioxidant capacity of plasma , MDA and inflammatory markers will be measured

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111715424N1**

Registration date: **2014-03-01, 1392/12/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-01, 1392/12/10

Registrant information

Name

MAjid Mohamadshahi

Name of organization / entity

Ahvaz Jundishapur University of medical sciences

Country

Iran (Islamic Republic of)

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+98 912 439 2836

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-10-07, 1392/07/15

Expected recruitment end date

2014-01-18, 1392/10/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sesamin supplementation on the serum levels of some proteolytic enzymes inflammatory , oxidative stress , cyclooxygenase 2 and lipid profile in rheumatoid arthritis women- triple blind Clinical trial

Public title

Effect of sesamin supplementation in rheumatoid arthritis women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate in study; Clinical diagnosis of rheumatoid arthritis (meeting the American college of rheumatology 1987 criteria); No smoking or

addiction; No drug type and dose fluctuation since 1 month prior to the study and during intervention period ; Not having severe cardiovascular; hepatic; kidney; gastrointestinal; thyroid; parathyroid diseases; diabetes and inflammation; Not using medications except for AR conventional drugs; No pregnancy or lactation Exclusion criteria: developing illnesses which need particular cures or interfere with intervention such as increasing the disease activity or trauma; alcoholic; sensitivity to sesame

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple 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 Ahvaz Jundishapur University of medical sciences

Street address

Ahvaz Jundishapur University of Medical Science
Ahvaz, Golestan Ave.

City

Ahvaz

Postal code**Approval date**

2013-10-06, 1392/07/14

Ethics committee reference number

ajums.REC.1392.133

Health conditions studied**1****Description of health condition studied**

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Seropositive rheumatoid arthritis

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

Total antioxidant capacity (TAC)

Timepoint

Before the intervention and 6 weeks after intervention

Method of measurement

ELISA

Secondary outcomes**1****Description**

TNF-alpha

Timepoint

Before the intervention and 6 weeks after intervention

Method of measurement

ELISA

2**Description**

Interlukin 6

Timepoint

Before the intervention and 6 weeks after intervention

Method of measurement

ELISA

Intervention groups**1****Description**

Intervention group: Sesamine supplement, 200 mg caps per day for 6 weeks

Category

Treatment - Drugs

2**Description**

Placebo group: placebo caps for 6 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rheumatology clinic of Firuzgar hospital

Full name of responsible person

Dr. Majid Mohamadshahi
Street address
Kianpars Ave
City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences
Full name of responsible person
Dr. Fegghi
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Ahvaz Jundishapur University of Medical Science
Ahvaz, Golestan Ave.
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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

Vice chancellor for research, Ahvaz Jundishapur
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
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Full name of responsible person
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Person responsible for updating data

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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