Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

Phone

+98 912 439 2836

Email address

mohamadshahi-m@ajums.ac.ir

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. Feghhi

Street address

Ahvaz Jundishapur University of Medical Science Ahvaz, Golestan Ave.

City

Ahvaz

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

Ahvaz Jundishapur University of medical sciences

Full name of responsible person

Dr. Majid Mohamadshahi

Position

Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of medical sciences, Dep. of nutrition, Paramedical faculty, Golestan Ave.

City

Ahvaz

Postal code

Phone

+98 61 1333 7079

Fax

Email

Mohamadshahi-m@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of medical sciences

Full name of responsible person

Dr. Majid mohamadshahi

Position

Assistant Professor

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of medical sciences, Dep. of nutrition, Paramedical faculty, Golestan Ave.

City

Ahvaz

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Phone

+98 61 1333 7079

Fax

Email

Mohamadshahi-m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of medical sciences

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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