Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The effect of astaxanthin supplementation on antioxidant status, inflammation status, disease severity and physical performance in patients with rheumatoid arthritis

Protocol summary

Study aim

Determining the effect of astaxanthin supplementation on antioxidant status, inflammation status, disease severity, and physical performance in patients with rheumatoid arthritis

Design

The clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. A table of random numbers is used for randomization

Settings and conduct

The current study is a double-blind, randomized, placebo-controlled clinical trial that will be conducted on adult patients with rheumatoid arthritis. Patients will be randomly divided into 2 groups (30 people) to receive astaxanthin supplement or placebo using a random numbers table. The blood test will e checked and other variables of the study are also examined before and after the intervention (60 days). To know that people are using the capsules ,the empty packages are delivered.

Participants/Inclusion and exclusion criteria

Age between 18 and 65 years old; Rheumatoid arthritis diagnosis by a specialist physician based on criteria (ACR); Having a disease activity score (DAS) higher than 3.2; Willingness to participate in the study and complete the consent form before starting the supplement therapy; Not taking herbal and medicinal supplements, especially antioxidant supplements, in the three months before the start of the study; Having a body mass index of 18.5 to 40

Intervention groups

The astaxanthin supplement and placebo will be delivered to the subjects in 20 mg capsulse, which will be consumed in capsule form along with a specified main meal for 60 days, along with the routine medical treatments prescribed by the doctor

Main outcome variables

Muscle strength; serum level of Interleukin 6 (IL-6); serum level of Malondialdehyde (MDA); Total antioxidant capacity (TAC); Red blood cell sedimentation rate (ESR); CRP serum level; Disease Activity Score (DAS-28); Visual Analogue Scale (VAS); Health Assessment (HAQ)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200429047235N2**
Registration date: **2024-01-06, 1402/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-06, 1402/10/16**
Update count: **0**

Registration date

2024-01-06, 1402/10/16

Registrant information

Name

Marzieh Kafeshani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of astaxanthin supplementation on antioxidant status, inflammation status, disease severity and physical performance in patients with rheumatoid arthritis

Public title
The effect of astaxanthin on rheumatoid arthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 65 years Rheumatoid arthritis diagnosis by a specialist physician based on criteria (ACR) Having a disease activity score (DAS) higher than 3.2 Willingness to participate in the study and complete the consent form before starting the supplement therapy Not taking herbal and medicinal supplements, especially antioxidant supplements, in the three months before the start of the study Having a body mass index of 18.5 to 40
Exclusion criteria:
Pregnancy and breastfeeding Smoking and being exposed to cigarette smoke on a daily basis Consumption of alcoholic beverages Following a special diet or exercise program Suffering from diseases such as diabetes mellitus, high blood pressure, thyroid disorder, kidney failure, liver dysfunction, Cushing's syndrome Inflammatory bowel diseases (Crohn's and ulcerative colitis) Using traditional medicine methods in the last 3 months Infectious rheumatoid arthritis Having a history of bariatric surgery Consumption of less than 80% of the total astaxanthin food supplement
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients stratified based on used drugs and BMI then randomly allocated into two groups using permuted random blocks of size 4.
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo and supplement are completely similar in appearance and will be coded by someone other than the researcher so that the researcher is not involved in the grouping process.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Medical Ethics Department, 1st Floor, Building No. 3, School of Medicine, Isfahan University of Medical Sciences, Hezarjerib Street
City
Esfahan
Province
Isfehan
Postal code
8174673461
Approval date
2023-11-26, 1402/09/05
Ethics committee reference number
IR.MUI.PHANUT.REC.1402.041

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis
ICD-10 code
M06.9
ICD-10 code description
Rheumatoid arthritis

Primary outcomes

1

Description
antioxidant status
Timepoint
The patient's antioxidant status will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Blood tests

2

Description
inflammation status
Timepoint
The measurement of inflammation will be done at the beginning of the study (before the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
blood tests

3

Description
Physical performance score
Timepoint
Physical performance will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Disease activity score-28 will be used to measure the physical performance score.

4

Description
Illness severity
Timepoint
The severity of the disease will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Visual Analogue Scale (VAS) will be used to measure the illness severity.

5

Description
Health evaluation
Timepoint
The patient's health will be evaluated at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Health Assessment Questionnaire (HAQ) will be used to assess the patient's health.

Secondary outcomes

1

Description
grip strength
Timepoint
Muscle strength will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Hand grip will be used to measure grip strength.

2

Description
C reactive protein (CRP)
Timepoint
The serum level of C-reactive protein will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Blood test

3

Description
Red blood cell sedimentation rate
Timepoint
Red blood cell sedimentation rate will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Blood test

4

Description
Interleukin 6 serum level
Timepoint
Interleukin-6 serum levels will be measured at the beginning of the study (before the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Blood test

5

Description
Malondialdehyde serum level
Timepoint
The measurement of serum malondialdehyde level will be done at the beginning of the study (before the start of the intervention) and 60 days after the start of taking the supplement (the end of the intervention).
Method of measurement
Blood test

6

Description
Total antioxidant capacity (TAC)
Timepoint
Total antioxidant capacity will be measured at the beginning of the study (before the start of the intervention) and 60 days after the start of the supplement (the end of the intervention).
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Astaxanthin is a natural carotenoid from the xanthophyll group, which exists in different amounts in different marine organisms such as algae, shrimp, crab, yeast, and salmon. Its main role is to create a desirable orange-red color in these organisms. Also, astaxanthin is a strong biological antioxidant and has the ability to inhibit free radicals. Individuals in the intervention group will receive a daily astaxanthin capsule made by the "Life Refreshing Biotechnology" company located in Al-Zahra University after lunch. By reviewing the relevant articles and the safe amount of astaxanthin consumption, the appropriate dose for astaxanthin supplement based on previous studies will be 20 mg per day in the form of oral capsules.

Category
Treatment - Drugs

2

Description
Control group: The placebo is prepared from Foodchem company and it is made in capsule form and distributed to the patients. The placebo is maltodextrin powder (corn starch) and is completely safe in terms of health.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Rheumatology doctor's office

Full name of responsible person
Ani Grigorian

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4th floor, Sepahan 2 building, Sepahan Alley, Amadegah St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Gholamreza Askari

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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
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Marzieh Kafeshani

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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student

Latest degree
Bachelor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available