Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of anti-inflammatory diet and flax seed on disease activity, inflammatory factors and quality of life in rheumatoid arthritis patients

Protocol summary

Study aim

Effect of anti-inflammatory diet with flaxseed on inflammatory factors, quality of life and disease activity criteria in people with rheumatoid arthritis

Design

In this double-blind study, we will test the effect of anti-inflammatory diet with this powder on disease activity, inflammatory factors, and quality of life in 120 patients. Patients are randomly divided into control and anti-inflammatory diet groups. At the beginning and at the end of the intervention, SF-36 and HAQ questionnaires will be completed. Finally, statistical analysis will be done using SPSS19 software.

Settings and conduct

Hafez Hospital of Shiraz, informed by patients informed consent, will be given to the intervention group anti-inflammatory training intervention and daily consumption of 30 grams of flaxseed powder using modular are recommended. questionnaires are completed and blood sampling in two stages At the end of the 3-month intervention, healthy control diet and toasted wheat powder will be given to the control group.During the study period, any changes in drug use will be recorded. Diet compliance is assessed weekly by telephone and any problems and side effects will be recorded.

Participants/Inclusion and exclusion criteria

Disease duration of at least 6 months, active disease with DAS28 criterion greater than 2.6 that is clinically established and controlled by the disease and range in age from 18 to 70 years. Individuals will not be included in the study if they have infectious diseases, cancer, and other inflammatory diseases such as liver and kidney failure, adherence to specific diets, drug dependence, alcohol consumption, and repeated use of herbal remedies.

Intervention groups

People with rheumatoid arthritis who are eligible for the study and have been enrolled with consent.

Main outcome variables

Anti-CCP, hs-CRP, hs-CRP, EMS, ESR, DAS28, TJC, ESR, VAS, IL6, rheumatoid factor (RF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190923044858N1**
Registration date: **2020-02-06, 1398/11/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-06, 1398/11/17**
Update count: **0**

Registration date

2020-02-06, 1398/11/17

Registrant information

Name

Maryam Ghaseminasabparizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3212 2566

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-05-21, 1399/03/01

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

Scientific title
Evaluating the effect of anti-inflammatory diet and flax seed on disease activity, inflammatory factors and quality of life in rheumatoid arthritis patients

Public title
Evaluating the effect of anti-inflammatory diet and flax seed on disease activity in rheumatoid arthritis patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Disease duration of at least 6 months, active disease with DAS28 criterion greater than 2.6, clinically established and controlled by the drugs and age range 18 to 70 years.
Exclusion criteria:
Individuals will not be included in the study if they have infectious diseases, cancer, and other inflammatory diseases such as liver and kidney failure, adherence to specific diets, drug dependence, alcohol consumption, and repeated use of herbal remedies.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into 2 groups (anti-inflammatory regimen with drug administration and control group with usual regimen with drug administration). Statistical software willbe randomization tool.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is blinded to the use of flaxseed or placebo. Flaxseed and roasted wheat are powdered and packaged by someone other than the researcher and identified by the letters A and B.
Placebo
Used
Assignment
Other
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Headquarters of Shiraz University of Medical Sciences, Zand Street, opposite Palestine Street, Shiraz
City
Shiraz
Province
Fars
Postal code
Approval date
2019-10-09, 1398/07/17
Ethics committee reference number
IR.SUMS.REC.1398.892

Health conditions studied

1

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

Primary outcomes

1

Description
Interlukin6
Timepoint
The beginning and the end of the study
Method of measurement
laboratory kit

2

Description
Anti-CCP
Timepoint
The beginning and the end of the study
Method of measurement
laboratory kit

3

Description

DAS28

Timepoint

The beginning and the end of the study

Method of measurement

Through examination

4

Description

Early Morning Stiffness

Timepoint

The beginning and the end of the study

Method of measurement

questionnaire

5

Description

Visual Analogue Scale

Timepoint

The beginning and the end of the study

Method of measurement

questionnaire

6

Description

Erythrocyte Sedimentation Rate

Timepoint

The beginning and the end of the study

Method of measurement

laboratory kit

Secondary outcomes

1

Description

Weight

Timepoint

The beginning and the end of the study

Method of measurement

Digital scales

2

Description

Waist

Timepoint

The beginning and the end of the study

Method of measurement

Tape measure

3

Description

Health Status

Timepoint

The beginning and the end of the study

Method of measurement

Health Status Questionnaire (SF-36)

4

Description

Health assessment

Timepoint

The beginning and the end of the study

Method of measurement

Stanford health assessment questionnaire(HAQ 8-item)

5

Description

3 days food record

Timepoint

The beginning, middle and end of the study

Method of measurement

food record

Intervention groups

1

Description

Intervention group1: Anti-inflammatory diet and flaxseed powder (30 g daily in two 15-g serving) for 3 months of diet and consumption of flaxseed

Category

Treatment - Other

2

Description

Intervention group II: Normal diet and flaxseed powder (30 g daily in two 15 gm serving) for 3 months

Category

Treatment - Other

3

Description

Control group: Normal diet and roasted wheat powder as placebo (30 g daily in two 15 gm serving) for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Masoumeh Akhlaghi

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School of Nutrition and Food Sciences, Razi Blvd, Shiraz, Iran

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Sponsors / Funding sources

1

Sponsor
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Shiraz University of Medical Sciences
Full name of responsible person
Masoumeh Akhlaghi
Position
Associate Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available