Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of the MIND diet with and without sesame meal tablets on clinical status in patients with rheumatoid arthritis

Protocol summary

Study aim

The effect of Mind diet with and without sesame meal tablets on clinical status in rheumatoid arthritis patients

Design

This factorial design study will involve 80 rheumatoid arthritis patients. The participants will be randomly assigned to one of four intervention groups for three months using the block randomization method. During the study, the researcher will keep in touch with the patients to address any issues.

Settings and conduct

This study will be conducted in Shahid Sadoughi Hospital, Yazd. Rheumatoid arthritis patients will be selected according to the opinion of a rheumatology specialist. At the start, participants will complete consent forms and general information questionnaires. To assess biochemical factors, 10 cc of venous blood samples and stool samples will be collected from all eligible participants. Patients and researchers will be unaware of the type of pill taken (supplement or placebo). At the end of the research, measurements will be taken again.

Participants/Inclusion and exclusion criteria

Rheumatoid arthritis diagnosed by doctor Age 18 to 70 years Completion of written consent Lack of pregnancy and breastfeeding, special diet, smoking, use alcohol, taking OCPs, suffering from chronic diseases and diseases related to weight change, taking estrogenic and hormonal medications, weight loss medications, recent surgery, taking supplements containing sesame compounds or sesame meal

Intervention groups

1- sesame meal supplement + standard diet, 2- placebo + standard diet, 3- MIND diet + placebo and 4- sesame meal supplement + MIND diet

Main outcome variables

CD40 and STAT4 gene expression, anxiety and depression, fatigue, sleep quality, total antioxidant capacity, nitric oxide, malondialdehyde, C-reactive protein, DAS28, quality of life with 36 questions (SF-36), FBS, Serum insulin, Homa-ir, Hb-A1c, insulin quicki, LDL, HDL, TG, total cholesterol, AST,ALT,LDH,Cr,eGFR

General information

Reason for update

Adding stool sample collection and liver and kidney function tests (aspartate aminotransferase, alanine aminotransferase, lactate dehydrogenase, creatinine, and glomerular filtration rate estimation) to the study protocol, with the aim of increasing the comprehensiveness of biological sample collection and enabling additional analyses related to the gut microbiome.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240710062384N1**
Registration date: **2024-07-17, 1403/04/27**
Registration timing: **prospective**

Last update: **2026-06-15, 1405/03/25**
Update count: **1**

Registration date

2024-07-17, 1403/04/27

Registrant information

Name

Negin Tahvilian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2024-08-22, 1403/06/01
Expected recruitment end date
2025-08-23, 1404/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of the MIND diet with and without sesame meal tablets on clinical status in patients with rheumatoid arthritis

Public title
Effect of Mind diet and sesame meal tablets on rheumatoid arthritis
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Suffering from rheumatoid arthritis as diagnosed by a doctor
Exclusion criteria:
Unwillingness to participate in the study Pregnancy and breastfeeding Smoking and alcohol consumption Use of oral contraceptives Suffering from chronic diseases including kidney, respiratory, heart diseases, uncontrolled diabetes (according to the doctor's opinion and diagnosis) and diseases related to weight change. Use of estrogenic and hormonal drugs Use of weight loss drugs in the last 3 months Following a special diet in the last month Recent surgery within the last 6 months Consuming supplements containing sesame compounds or sesame flour before starting the intervention
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the studied groups, the block randomization method will be used. The statistical consultant will design the blocks using statistical software. Patients are placed in 4 equal groups (drug A, B, regimen C, D) based on a random table with 8 blocks designed using Random allocation software. In order to randomly assign 80 patients to four treatment groups, the first 10 blocks of 8 different letters A, B, C, and D are created. Then these blocks are numbered from one to ten. In the next step, each of these blocks is randomly selected by lottery. The obtained combinations of letters will be placed one by one in 80 separate and closed envelopes, and with each patient's visit, an envelope will be opened to assign the patient to the desired group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences
Street address
Shahid Sadoughi University of Medical Sciences, Daneshjoo Blvd., Yazd.
City
Yazd
Province
Yazd
Postal code
8916188635
Approval date
2024-02-28, 1402/12/09
Ethics committee reference number
IR.SSU.SPH.REC.1403.009

Health conditions studied

1

Description of health condition studied
Rheumatoid Arthritis
ICD-10 code
M05
ICD-10 code description
Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description
Total antioxidant capacity
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum and total antioxidant capacity measurement kit

2

Description
Nitric oxide
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum and nitric oxide measurement kit

3

Description
CD40 gene expression
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Gene expression by REALTIME method

4

Description
Malondialdehyde
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum and Malondialdehyde measurement kit

5

Description
C reactive protein
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum and C reactive protein measurement kit

6

Description
Disease Activity Score in 28 Joints (DAS28)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Doctor-supervised questionnaire

7

Description
STAT4 gene expression
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Gene expression by REALTIME method

8

Description
Fatigue
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Smiths Fatigue Questionnaire (MFI)

9

Description
Sleep quality
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Petersburg Sleep Questionnaire - PSQL

10

Description
Stress and depression
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Anxiety and Depression Questionnaire

11

Description
Quality of Life
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Quality of life questionnaire with 36 questions (SF-36)

12

Description
Fasting blood sugar
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

13

Description
Serum insulin

Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

14

Description
HOMA-IR
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

15

Description
HbA1c
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

16

Description
Insulin quicki
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

17

Description
Low-density lipoprotein (LDL)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

18

Description
High-density lipoprotein (HDL)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

19

Description
Triglyceride (TG)
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

20

Description
Total cholesterol
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

21

Description
Rheumatoid factor test
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Quantitative Biosystem Method with BA400 Device

22

Description
Bacteria feces
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
CFU count of fecal bacteria by Real-time PCR method

23

Description
Aspartate Aminotransferase
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

24

Description
Alanine Aminotransferase
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement

Using patients' serum

25

Description
Lactate Dehydrogenase
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

26

Description
Creatinine
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using patients' serum

27

Description
Estimated Glomerular Filtration Rate
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (after three months of the intervention)
Method of measurement
Using the CKD-EPI formula

Secondary outcomes

1

Description
Body mass index
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study
Method of measurement
Using height and weight and formula

2

Description
Nutrient intake
Timepoint
at the beginning of the study on 3 days of the week (one day on the weekend, two days during the week) and at the end of the study on 3 days of the week (one day on the weekend, two days during the week)
Method of measurement
24 hour dietary recall questionnaire

3

Description
Blood pressure
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study
Method of measurement
Omron digital blood pressure monitor

Intervention groups

1

Description
Intervention group: Sesame meal supplement + MIND diet. Sesame meal supplement in the form of pressed tablets is prepared from powdered sesame meal in the pharmaceutical laboratory of Shahid Sadoughi University of Medical Sciences, Yazd. Each tablet will contain 830 grams of sesame meal and three tablets per day (about 2.5 grams of sesame meal) will be consumed by the participants for 3 months. The MIND diet will be designed with a macronutrient combination of 32% fat - 50% carbohydrate - 18% protein. The energy required by people will be calculated using the Harris-Benedict formula, physical activity level, and based on body mass index and ideal weight. Patients are asked not to change their physical activity. At the beginning of the study, a group diet training session will be held for 30 minutes with the help of educational slides and a private training session. Then, patients will be contacted every week to answer possible questions (also, patients will be members of answering groups on a social media platform 'Eitaa'). After one and a half months (middle of the study), the second group training session will be held with the help of training slides.
Category
Other

2

Description
Intervention group: Sesame meal supplement + standard diet. Sesame meal supplement in the form of pressed tablets is prepared from powdered sesame meal in the pharmaceutical laboratory of Shahid Sadoughi University of Medical Sciences, Yazd. Each tablet will contain 830 grams of sesame meal and three tablets per day (about 2.5 grams of sesame meal) will be consumed by the participants for 3 months. The Standard diet will be designed with a macronutrient combination of 32% fat - 50% carbohydrate - 18% protein. The energy required by people will be calculated using the Harris-Benedict formula, physical activity level, and based on body mass index and ideal weight. Patients are asked not to change their physical activity. At the beginning of the study, a group diet training session will be held for 30 minutes with the help of educational slides and a private training session. Then, patients will be contacted every week to answer possible questions (also, patients will be members of answering groups on a social media platform 'Eitaa'). After one and a half months (middle of the study), the second group training session will be held with the help of training slides.
Category

Other

3

Description

Control group: Placebo + standard diet. Placebo is prepared in the form of pressed tablets from Avicel and lactose powder in the pharmacy laboratory of Shahid Sadoughi University of Medical Sciences, Yazd. Each pill will contain 830 grams of Avicel and lactose powder with a ratio of 1 to 1, and participants will take three pills per day (about 2.5 grams per day) for 3 months. The Standard diet will be designed with a macronutrient combination of 32% fat - 50% carbohydrate - 18% protein. The energy required by people will be calculated using the Harris-Benedict formula, physical activity level, and based on body mass index and ideal weight. Patients are asked not to change their physical activity. At the beginning of the study, a group diet training session will be held for 30 minutes with the help of educational slides and a private training session. Then, patients will be contacted every week to answer possible questions (also, patients will be members of answering groups on a social media platform 'Eitaa'). After one and a half months (middle of the study), the second group training session will be held with the help of training slides.

Category

Placebo

4

Description

Control group: Placebo + MIND diet. Placebo is prepared in the form of pressed tablets from Avicel and lactose powder in the pharmacy laboratory of Shahid Sadoughi University of Medical Sciences, Yazd. Each pill will contain 830 grams of Avicel and lactose powder with a ratio of 1 to 1, and participants will take three pills per day (about 2.5 grams per day) for 3 months. The MIND diet will be designed with a macronutrient combination of 32% fat - 50% carbohydrate - 18% protein. The energy required by people will be calculated using the Harris-Benedict formula, physical activity level, and based on body mass index and ideal weight. Patients are asked not to change their physical activity. At the beginning of the study, a group diet training session will be held for 30 minutes with the help of educational slides and a private training session. Then, patients will be contacted every week to answer possible questions (also, patients will be members of answering groups on a social media platform 'Eitaa'). After one and a half months (middle of the study), the second group training session will be held with the help of training slides.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Mahdieh Hosseinzadeh

Street address

Shahid Qandi Boulevard, Ibn Sina Boulevard, Yazd

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Province

Yazd

Postal code

8785789158

Phone

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Email

international@ssu.ac

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Amin Salehi Abargoui

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Imam Reza Research Educational Complex, Student Blvd, Imam Hossein Square

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Province

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Postal code

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person
Mahdieh Hosseinzadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Negin Tahvilian
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Title and more details about the data/document
All potential data that will be published as papers can be shared after de-identifying individuals.
When the data will become available and for how long
Access will start 9 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutions, as well as people working in the industry.
Under which criteria data/document could be used
Non-personally identifiable data will be used for the study of researchers and people working in the industry.
From where data/document is obtainable
For access to data, contact the person responsible for the study. Dr. Mahdieh Hosseinzadeh, a member of the faculty of Yazd University of Medical Sciences. Email: hoseinzade.mahdie@gmail.com
What processes are involved for a request to access data/document
Send an email to the introduced person, after checking the identity and the reason for the request, the data will be shared within fourteen days, emphasizing the confidentiality of the requested data.

Comments