Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The evaluation of the effects of intermittent fasting diet on clinical symptoms, inflammation, and oxidative stress in overweight and obese postmenopausal women with rheumatoid arthritis

Protocol summary

Study aim

Determining the effects of intermittent fasting on clinical symptoms, inflammation and oxidative stress in postmenopausal, overweight and obese women with rheumatoid arthritis

Design

A clinical trial with a control group, with parallel groups, on 44 patients

Settings and conduct

This study will be conducted as a parallel clinical trial on patients with rheumatoid arthritis. Participants from the rheumatology clinic of Valiasr Hospital in Tehran will be included based on the inclusion criteria. Informed written consent is obtained from the participants, then they are randomly assigned to one of the two groups of 16:8 intermittent fasting diet along with nutritional recommendations based on the permuted block randomization method. The study period will be 8 weeks. At the beginning and end of the study, 10 milliliters of venous blood will be taken from the patients to evaluate biochemical indicators, and also the anthropometric characteristics, food intake and activity and body composition of the patients will be collected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with Rheumatoid Arthritis; menopause; overweight or obese. Exclusion criteria: alcohol consumption; pregnancy; breastfeeding; change in medication regime in the last 3 months.

Intervention groups

The people of the intervention group have an intermittent fasting diet of the type (16:8) in which people are only allowed to receive water and non-energy drinks, tea, coffee and sugar-free gums for 16 hours and for 8 hours In the case of free consumption, they will receive food along with healthy diet recommendations for eight weeks, and the control group will receive their usual diet along with healthy diet recommendations in the same way as the intervention group, for eight weeks. will do

Main outcome variables

Clinical symptoms; inflammation and oxidative stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230217057441N1**
Registration date: **2023-03-05, 1401/12/14**
Registration timing: **prospective**

Last update: **2023-03-05, 1401/12/14**
Update count: **0**

Registration date

2023-03-05, 1401/12/14

Registrant information

Name

mahsa ranjbar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4223 9415

Email address

mahsa.rnjb99@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effects of intermittent fasting diet on clinical symptoms, inflammation, and oxidative stress in overweight and obese postmenopausal women with rheumatoid arthritis

Public title

Evaluation of the effects of fasting diet in patients with rheumatoid arthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Women Body mass index 25-35 kg/m2 Age range between 50 and 70 years Menopause Diagnosed with rheumatoid arthritis by a rheumatologist for more than 6 months Moderate to low rheumatoid arthritis disease activity (i.e. disease activity score <5.1) Following a stable drug regimen for 3 months before the intervention Not receiving non-steroidal anti-inflammatory drugs (NSAIDs) Willingness to cooperate

Exclusion criteria:

Consumption of alcohol Suffering from other autoimmune diseases, kidney diseases, pancreatitis, gallstones, cancer Pregnancy and breastfeeding Following a special diet in the last three months Changing the medication regimen from 3 months

Age

From **50 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will using the permuted block technique using 4 blocks, which will be based on the BMI variable and the medications received, and to one of the two groups of 16:8 intermittent fasting diet along with nutritional recommendations to receive healthy food for Rheumatoid arthritis patients and the other group will be assigned a regular diet along with the nutritional recommendations of receiving healthy food for rheumatoid arthritis patients, similar to the recommendations given to the fasting group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of Imam Khomeini Hospital Complex - Tehran University of Medical Scienc

Street address

Imam Khomeini Hospital Complex, Tohid Squre

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-02-14, 1401/11/25

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.376

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

In this study, HAQ score is considered as the primary outcome

Timepoint

Investigating the effects of clinical symptoms, inflammation and oxidative stress at the beginning of the study (before the start of the intervention) and 8 weeks after the start of the intermittent fasting diet in postmenopausal, overweight and obese women with rheumatoid arthritis

Method of measurement

Questionnaire for health assessment-disability index: In order to evaluate the performance of patients, it will be completed by the project manager at the beginning and end of the study, and by asking the patients.

Secondary outcomes

1

Description
The level of total oxidant and antioxidant capacity
Timepoint
The effect of intermittent fasting diet on the level of total oxidant and antioxidant capacity at the beginning of the study (before the start of the intervention) and 8 weeks after the start in postmenopausal, overweight and obese women with rheumatoid arthritis.
Method of measurement
Calorimetry kit: It will be measured from colorimetric methods with microplate spectrophotometer to measure TAC and TOC at the beginning and end of the study.

2

Description
Symptoms of rheumatoid arthritis
Timepoint
The effect of intermittent fasting on the symptoms of rheumatoid arthritis at the beginning of the study (before the intervention) and 8 weeks after the intervention in postmenopausal, overweight and obese women with rheumatoid arthritis.
Method of measurement
Questionnaire to evaluate the degree of swelling and tenderness of joints in rheumatoid arthritis patients, questionnaire of perceived visual pain of the patient, questionnaire of health-disability index, questionnaire to evaluate the level of disease activity by the patient, questionnaire to evaluate the level of disease activity by the researcher, questionnaire to evaluate morning stiffness

3

Description
Inflammation
Timepoint
The effect of intermittent fasting diet on inflammation at the beginning of the study (before the start of the intervention) and 8 weeks after the start in postmenopausal, overweight and obese women with rheumatoid arthritis
Method of measurement
Erythrocyte sedimentation rate or ESR and C-reactive protein or CRP

Intervention groups

1

Description
Intervention group: The people of the intervention group have an intermittent fasting diet of the type (16:8) in which people are only allowed to receive water and non-energy drinks, tea, coffee and sugar-free gums for 16 hours and for 8 hours In the free mode, they will receive food along with healthy diet recommendations for eight weeks
Category
Lifestyle

2

Description
Control group: The control group will receive their usual diet, along with the same healthy diet recommendations as the intervention group, for eight weeks.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Kurosh Djafarian
Street address
Imam Khomeini Hospital Complex, Tohid Squre
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Futohi
Street address
Tehran Province, Tehran,Keshavarz Blvd., corner of Quds St., Central Organization of the University, 6th floor
City
tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Email
vcr@sina.tums.ac.ir
Grant name
Research assistant of Tehran University of Medical Sciences
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Kurosh Djafarian
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Tehran Province, Tehran, Hojjatdoust St
City
Tehran
Province
Tehran
Postal code
1416643931
Phone
+98 21 8895 5975
Email
info_snsd@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Korush Djafarian
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Nutrition
Street address
Tehran Province, Tehran, Hojjatdoust St
City
Tehran
Province
Tehran
Postal code
1416643931
Phone
+98 21 8895 5975
Email
info_snsd@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Kurosh Djafarian
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Nutrition
Street address
Tehran Province, Tehran, Hojjatdoust St
City
Tehran
Province
Tehran
Postal code
1416643931
Phone
+98 21 8895 5975
Email
info_snsd@tums.ac.ir

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