Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The Evaluation of the effects of intermittent fasting diet on metabolic parameters, antioxidant indices and lipid peroxidation in overweight and obese menopause women with rheumatoid arthritis: a clinical trial

Protocol summary

Study aim
Determining the effects of intermittent fasting on metabolic parameters, antioxidant indices and lipid peroxidation in overweight and obese menopause 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 shariati 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 manifestations; metabolic parameters; antioxidant indices and lipid peroxidation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220929056058N1**
Registration date: **2024-01-15, 1402/10/25**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-15, 1402/10/25**
Update count: **0**

Registration date
2024-01-15, 1402/10/25

Registrant information

Name
Aryan Tavakoli

Name of organization / entity

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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
2024-05-19, 1403/02/30

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 metabolic parameters, antioxidant indices and lipid peroxidation in overweight and obese menopause women with rheumatoid arthritis: a clinical trial

Public title
Investigating the effects of intermittent fasting in improving the conditions of patients with rheumatoid arthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women Body mass index 25-35 kg/m2 Age range between 50 and 70 years Menopause 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
Research Ethics Committees of Shariati Hospital
Street address
Jalal-e-Al-e-Ahmad Hwy
City
Tehran
Province
Tehran
Postal code
14117 13135
Approval date
2023-12-13, 1402/09/22
Ethics committee reference number
IR.TUMS.SHARIATI.REC.1402.122

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.

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
Fasting blood sugar
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Glucose oxidase enzymatic method using commercial kits of Pars Azmoon company in terms of (mg/dL

4

Description
Total cholesterol
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Measurement of total cholesterol level using Pars Azmoon kits and auto analyzer

5

Description
Triglyceride
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Measurement of triglyceride level using Pars Azmoon kits and auto analyzer

6

Description
HDL cholesterol
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Measurement of HDL cholesterol level using Pars Azmoon kits and auto analyzer

7

Description
LDL cholesterol
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Measurement of LDL cholesterol by Friedwald formula [LDL = Chol - (TG / 5 + HDL)], with plasma triglyceride concentrations below 400 mg/dL.

8

Description
Aspartate transaminase enzyme (AST)
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Proposed IFCC method - Photometry Pars azmoon Kit

9

Description
Alanin transaminase enzyme (ALT)
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Proposed IFCC method - Photometry Pars azmoon Kit

10

Description
Fasting blood insulin level
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Special laboratory kit

11

Description
HOMA-IR
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Using the formula

12

Description
QUICKI
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Using the formula

13

Description
Physical activity
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Record physical activity

14

Description
Myleoperoxidase activity
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Elisa Method

15

Description
Catalase
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Elisa Method

16

Description
Superoxide dismutase
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Elisa Method

17

Description
Nitric oxide
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Elisa Method

18

Description
Malondialdehyde
Timepoint
At the beginning and end of the study (after 8 weeks (56 days))
Method of measurement
Elisa Method

Secondary outcomes

empty

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
Shariati Hospital
Full name of responsible person
Gholamreza Mohammadi Farsani
Street address
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Email
shariatihosp@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
Central Organization of the University, 6th floor, corner of Quds St., Keshavarz Blvd.
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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
Aryan tavakoli
Position
Student
Latest degree
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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