

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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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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

AgeFrom **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

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Jalal-e-Al-e-Ahmad Hwy

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Province

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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

Myeloperoxidase 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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
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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