Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

To investigate the effect of a 5:2 intermittent fasting diet with high protein content versus daily calorie restriction balanced diet on anthropometric indices, body composition analysis, functional status, pain intensity, and serum markers of inflammation and oxidative stress in overweight and obese postmenopausal women with knee osteoarthritis

Protocol summary

Study aim

To determine the effect of a 5:2 intermittent fasting diet with high protein content compared to a balanced diet with daily calorie restriction on anthropometric indices, body composition analysis, functional status, pain intensity, and serum markers of inflammation and oxidative stress in overweight and obese postmenopausal women with knee osteoarthritis.

Design

Controlled clinical trial, with parallel groups, single-blind, randomized, phase 3 on 150 patients

Settings and conduct

The patients will be selected from among female patients referred to the Physical Medicine Clinic of Imam Reza Hospital in Tabriz with a diagnosis of knee osteoarthritis using a convenience sampling method and will be randomly assigned to receive two balanced low-calorie diets and a 5:2 intermittent fasting diet for 4 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of knee osteoarthritis by a physical medicine specialist Stopping the menstrual cycle naturally 12 months ago Body mass index of 25 kg/m2 and above Not having another inflammatory disease, such as rheumatoid arthritis No intra-articular injection for the past 3 months No oral medication (nonsteroidal anti-inflammatory drugs) for one week before study entry. Exclusion criteria: Daily calorie intake of less than 800 and more than 4200 kcal A deviation from a specific eating pattern due to medical or other reasons Use of dietary supplements, diuretics, or laxatives during the intervention period Participation in sports programs or changes in physical activity Failure to follow the recommended diet Use of weight-affecting medications

Intervention groups

Intervention group: 5:2 intermittent fasting diet with high protein content Control group: Balanced low-calorie diet

Main outcome variables

Anthropometric indices, body composition, functional status, pain level, serum markers of inflammation, and oxidative stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030424N13**
Registration date: **2025-06-07, 1404/03/17**
Registration timing: **prospective**

Last update: **2025-06-07, 1404/03/17**
Update count: **0**

Registration date

2025-06-07, 1404/03/17

Registrant information

Name

Neda Dolatkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date
2025-07-06, 1404/04/15
Expected recruitment end date
2026-07-06, 1405/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To investigate the effect of a 5:2 intermittent fasting diet with high protein content versus daily calorie restriction balanced diet on anthropometric indices, body composition analysis, functional status, pain intensity, and serum markers of inflammation and oxidative stress in overweight and obese postmenopausal women with knee osteoarthritis

Public title
5:2 intermittent fasting diet with high protein content in knee osteoarthritis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of knee osteoarthritis by a physical medicine specialist Stopping menstrual cycle naturally 12 months ago Body mass index of 25 kg/m2 and above Not having another inflammatory disease such as rheumatoid arthritis No intra-articular injection for the past 3 months No oral medication (nonsteroidal anti-inflammatory drugs) for one week prior to study entry.
Exclusion criteria:
Daily calorie intake of less than 800 and more than 4200 kcal A deviation from a specific eating pattern due to medical or other reasons Use of dietary supplements, diuretics, or laxatives during the intervention period Participation in sports programs or changes in physical activity Failure to follow the recommended diet Use of weight-affecting medications
Age
From **40 years** old to **70 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use a stratified block randomization method for allocation. The computer-generated code, created using SAS software version 8.01, will be used to create a randomized sequence by a statistician outside the project's research team. Randomization will be stratified based on body mass index and osteoarthritis severity (mild, moderate, and severe). Serially numbered, opaque, sealed packets will be used to ensure allocation
Blinding (investigator's opinion)
Single blinded
Blinding description
Blinding the patients is not feasible in this trial. A trained nutritionist will ban diet-related conversations between assessors and patients during the study. Outcome assessors and the person responsible for statistical analysis will be blinded to the type of interventions received until the end of the study
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5456754324
Approval date
2025-02-15, 1403/11/27
Ethics committee reference number
IR.TBZMED.REC.1403.1101

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17.0
ICD-10 code description
Primary gonarthrosis, bilateral

Primary outcomes

1

Description
Weight
Timepoint
Weight measurement at the beginning of the study (before the start of the intervention) and 1, 2, 3 and 4 months after the start of the intervention
Method of measurement
Seca digital scale

2

Description
Body mass index
Timepoint
Body mass index measurement at the beginning of the study (before the start of the intervention) and 1, 2, 3 and 4 months after the start of the intervention
Method of measurement
Calculation

3

Description
Body fat mass
Timepoint
Measurement of body fat mass at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Body analyzer

4

Description
Fat-free body mass
Timepoint
Measurement of fat-free body mass at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Body analyzer

Secondary outcomes

1

Description
Pain intensity
Timepoint
Pain intensity measurement at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Visual Analogue Scale

2

Description
Functional status
Timepoint
Measurement of functional status at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis Index (WOMAC)

3

Description
High-sensitivity C-reactive protein (hsCRP) level
Timepoint
Measurement of high-sensitivity C-reactive protein (hsCRP) levels at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Biochemical analysis

4

Description
Total antioxidant capacity (TAC) level
Timepoint
Measurement of total antioxidant capacity (TAC) levels at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Biochemical analysis

5

Description
Malondialdehyde (MDA) level
Timepoint
Measurement of Malondialdehyde (MDA) levels at the beginning of the study (before the start of the intervention) and 4 months after the start of the intervention
Method of measurement
Biochemical analysis

Intervention groups

1

Description
Intervention group: 5:2 fasting diet with high-protein intermittent content for 4 months (This diet involves maintaining normal eating habits for five consecutive days a week, maintaining an energy intake range of 1,400 to 1,600 kcal/day for women. On the remaining two days, a light fasting diet is adopted, limiting daily energy intake to 600 kcal/day. The percentage of protein in daily calories consumed is designed to be 2 grams per kilogram of body weight on all days of the week.)
Category
Treatment - Other

2

Description
Control group: Balanced low-calorie diet (500 kcal is

deducted from the average 3-day energy intake of the individual, and the diet will be designed with the following distribution: fat less than 30% of calories, carbohydrates 55-60% of calories, and protein 10-15% of calories)

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Neda Dolatkhah

Street address
Imam Reza Educational and Medical Center, opposite the Central Organization of the University, Golgasht Street

City
Tabriz

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East Azarbaijan

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5166614756

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Email
neda_dolatkhah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Khosro Adibkia

Street address
Vice Chancellor for Research and Technology, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golgasht Street

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Grant name

Grant code / Reference number
75837

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Neda Dolatkhah

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
Neda dolatkhah

Position
Assistant professor

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Neda Dolatkhah

Position
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Latest degree
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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