

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 Dolatkhan

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3336 1928

Email address

dolatkhan@tbzmed.ac.ir

Recruitment status

Recruitment complete

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

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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 Dolatkah

Street address

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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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 Dolatkah

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Neda dolatkah

Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Other areas of specialty/work

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the Central Organization of the University, Golgasht
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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