Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of a fasting-mimicking diet and synbiotic supplementation on SIRT1 gene expression, serum IGF-1 level, insulin resistance index, and metabolic parameters in obese adults with metabolic syndrome

Protocol summary

Study aim

Determining the effect of a fasting-mimicking diet and synbiotic supplementation on SIRT1 gene expression, serum IGF-1 levels, insulin resistance index, and metabolic parameters in obese adults with metabolic syndrome

Design

A three-arm, parallel-group, randomized, controlled clinical trial involving 186 participants. Randomization will be performed using a stratified approach with variable-sized blocks, based on gender and body mass index (BMI) categories. Outcome assessors and the data analyst will be blinded to group allocation.

Settings and conduct

This clinical trial will be conducted at the Imam Khomeini Hospital in Urmia. After screening and obtaining informed consent, participants will be randomly allocated to three groups and followed for 3 months. Outcome assessors and data analysts will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Major inclusion criteria before randomization: Age 18 to 55 years, both sexes, BMI greater than 30 kg/m², central obesity, and metabolic syndrome according to the International Diabetes Federation criteria. Major non-inclusion criteria before randomization: Chronic liver, kidney, or cardiovascular diseases, malignancy, inflammatory diseases or severe gastrointestinal disorders, uncontrolled thyroid disorders, pregnancy or breastfeeding, smoking or alcohol consumption, recent use of antibiotics or probiotic and prebiotic supplements, use of medications affecting metabolism, significant weight change during the previous three months

Intervention groups

Group 1: Continuation of the usual diet, general healthy eating recommendations, and daily use of one placebo capsule for 12 weeks.Group 2: Fasting mimicking diet for 3 months, consisting of one 5 day cycle each month with continuation of the usual diet on the remaining days.Group 3: Fasting mimicking diet similar to Group 2, along with daily use of one synbiotic capsule for 12 weeks.

Main outcome variables

SIRT1 gene expression; serum IGF-1; HOMA-IR; serum insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190317043084N2**
Registration date: **2026-10-19, 1405/07/27**
Registration timing: **prospective**

Last update: **2026-10-19, 1405/07/27**
Update count: **0**

Registration date

2026-10-19, 1405/07/27

Registrant information

Name
Maryam Afsharfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3275 2372
Email address
maryam.afshaar.1991@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date
2026-10-24, 1405/08/02
Expected recruitment end date
2027-01-23, 1405/11/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of a fasting-mimicking diet and synbiotic supplementation on SIRT1 gene expression, serum IGF-1 level, insulin resistance index, and metabolic parameters in obese adults with metabolic syndrome

Public title
Effects of a Fasting-Mimicking Diet and Synbiotic Supplementation in Obese Adults with Metabolic Syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants aged 18 to 55 years with obesity, defined as a body mass index (BMI) greater than 30 kg/m², and central obesity, defined as a waist circumference of 94 cm or more in men and 80 cm or more in women Meeting at least two of the metabolic criteria for metabolic syndrome Serum triglyceride level of 150 mg/dL or higher or receipt of specific pharmacological treatment HDL-C level lower than 40 mg/dL in men and lower than 50 mg/dL in women or receipt of relevant treatment Systolic blood pressure of 130 mmHg or higher and/or diastolic blood pressure of 85 mmHg or higher or use of antihypertensive medications Fasting blood glucose of 100 mg/dL or higher or a history of confirmed type 2 diabetes mellitus
Exclusion criteria:
Participants with chronic liver, kidney, or cardiovascular diseases Participants with malignancies Participants with inflammatory diseases or severe gastrointestinal disorders Participants with uncontrolled thyroid disorders Pregnant or breastfeeding women Current smoking or alcohol consumption Use of antibiotics within the previous three months Use of probiotic- or prebiotic-containing supplements within the previous three months Use of medications affecting metabolism Significant weight changes within the previous three months Known allergy or intolerance to the herbal components of the dietary intervention, the herbal teas used in the study, or the components of the synbiotic supplement
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **186**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of randomization and description of the method: Stratified block randomization with an allocation ratio of 1:1:1 and variable block sizes will be used Unit of randomization: Individual Stratification factors: Sex (female/male) and body mass index (BMI) in two strata of 30–34.9 and ≥35 kg/m² Randomization tool: The random allocation sequence will be computer-generated by an independent researcher who is not involved in the implementation of the study Generation of the random allocation sequence: For each stratum, a separate random allocation sequence will be generated using variable block sizes and an allocation ratio of 1:1:1 to the three study groups Allocation concealment: The allocation sequence will be placed in opaque, sealed, sequentially numbered envelopes, and the envelope corresponding to each participant will be opened only after eligibility criteria have been confirmed, written informed consent has been obtained, and the participant has been definitively enrolled in the study
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the dietary intervention, complete blinding of participants to receiving the FMD or usual diet is not feasible. However, participants will be blinded to the type of supplement received (synbiotic or placebo). The synbiotic supplement and placebo will be identical in appearance, packaging, and taste and will be provided in coded containers. The researcher responsible for implementing the intervention will be aware of the group allocation and the type of supplement received by each participant and therefore will not be blinded to group allocation. Outcome assessors and personnel responsible for data collection will be blinded to the participants' group allocation, and information regarding group assignment will not be disclosed to them. The data analyst will also be blinded to group allocation. Data will be provided using anonymous group codes, such as A, B, and C. The group codes will remain concealed from the data analyst until completion of the primary statistical analysis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
Department of Nutrition Sciences, Faculty of Medicine, Urmia University of Medical sciences, Nazlu road

City
Urmia

Province
West Azarbaijan

Postal code
5166796831

Approval date
2026-09-16, 1405/06/25

Ethics committee reference number
IR.UMSU.REC.1405.193

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
SIRT1 gene expression

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Using real-time polymerase chain reaction (Real-time PCR)

2

Description
serum IGF-1 level

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Using an enzyme-linked immunosorbent assay (ELISA) with a commercial kit.

3

Description
Insulin sensivity

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
It is calculated using fasting insulin and fasting glucose levels according to the following formula.

4

Description
Fasting blood glucose

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Fasting blood glucose will be measured in fasting serum samples using the enzymatic colorimetric method with commercial kits on an autoanalyzer (BT1500).

5

Description
Fasting serum insulin

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Fasting serum insulin will be measured using an ELISA kit and an ELISA reader (Stat Fax 4200), according to the manufacturer’s instructions.

6

Description
Total cholesterol

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Total cholesterol will be measured in fasting serum samples using enzymatic colorimetric kits from Pars Azmun and a BT1500 autoanalyzer, according to the manufacturer’s instructions.

7

Description
Triglycerides(TG)

Timepoint
Before the intervention and 3 months after the intervention

Method of measurement
Triglycerides will be measured in fasting serum samples using enzymatic colorimetric kits from Pars Azmun and a BT1500 autoanalyzer, according to the manufacturer’s instructions.

8

Description
HDL

Timepoint
Before the intervention and 3 months after the

intervention

Method of measurement

HDL will be measured in fasting serum samples using enzymatic colorimetric kits from Pars Azmun and a BT1500 autoanalyzer, according to the manufacturer's instructions.

9

Description

LDL

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

LDL will be measured in fasting serum samples using enzymatic colorimetric kits from Pars Azmun and a BT1500 autoanalyzer, according to the manufacturer's instructions.

10

Description

High-sensitivity C-reactive protein (hs-CRP)

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

High-sensitivity C-reactive protein (hs-CRP) will be measured in fasting serum samples using high-sensitivity ELISA kits and an ELISA reader (Stat Fax 4200), according to the manufacturer's instructions.

11

Description

Body weight

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Body weight will be measured with light clothing and without shoes using a calibrated digital scale (Beurer, Germany) with an accuracy of 0.1 kg.

12

Description

Body fat percentage

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Body fat percentage will be measured using a bioelectrical impedance analysis (BIA) body composition analyzer, InBody 270 (Korea), in a standing position without shoes.

13

Description

Muscle mass

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Body fat percentage will be measured using a bioelectrical impedance analysis (BIA) body composition analyzer, InBody 270 (Korea), in a standing position without shoes.

Secondary outcomes

1

Description

Changes in energy and macronutrient intake

Timepoint

At weeks 0, 6, and 12

Method of measurement

Based on a food frequency questionnaire (FFQ) and 24-hour dietary recalls

2

Description

Physical activity level

Timepoint

At weeks 0, 6, and 12

Method of measurement

Based on a METs questionnaire

Intervention groups

1

Description

Intervention group 1: Participants will receive a fasting mimicking diet for 3 months, consisting of one 5 day cycle each month, while continuing their usual diet on the remaining days. Energy intake will be approximately 1100 kcal on day 1 and 700 to 800 kcal on days 2 to 5. The diet will be plant based, low calorie, low protein, and designed with a higher proportion of unsaturated fats. Standardized daily food packs will be provided to participants. They will also take one placebo capsule daily for 12 weeks.

Category

Treatment - Other

2

Description

Intervention group 2: Participants will receive the same fasting mimicking diet as intervention group 1 for 3 months, along with one capsule of FamiLact synbiotic, manufactured by Zist Takhmir, Iran, daily for 12 weeks. Each capsule contains approximately 10^9 colony forming units of probiotics along with the prebiotic fructooligosaccharide.

Category

Treatment - Other

3

Description
Control group: Participants will continue their usual diet and receive general healthy eating recommendations. They will take one placebo capsule daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Urmia University of Medical Sciences
Full name of responsible person
Maryam Afsharfar
Street address
Department of Nutrition Sciences, Faculty of Medicine, Urmia University of Medical Sciences, Nazlu road
City
Urmia
Province
West Azarbaijan
Postal code
5166796831
Phone
+98 915 942 9362
Email
maryam.afshaar.1991@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Hamidreza Khalkhali
Street address
Department of Nutrition Sciences, Faculty of Medicine, Urmia University of Medical Sciences, Nazlu road
City
Urmia
Province
West Azarbaijan
Postal code
5166796831
Phone
+98 915 942 9362
Email
maryam.afshaar.1991@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Laleh Payahoo
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition Sciences, Faculty of Medicine, Urmia University of Medical Sciences, Nazlu road
City
Urmia
Province
West Azarbaijan
Postal code
5756115198
Phone
+98 44 3275 2372
Email
llllpayahoo44@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Laleh Payahoo
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition Sciences, Faculty of Medicine, Urmia University of Medical Sciences, Nazlu road
City
Urmia

Province
West Azarbaijan
Postal code
5756115198
Phone
+98 44 3275 2372
Email
lllllpayahoo44@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Maryam Afsharfar
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition sciences, Faculty of medicine, Urmia university of medical sciences, Nazlu road
City
Urmia
Province
West Azarbaijan
Postal code
5166796834
Phone
+98 44 3275 2372
Email
maryam.afshaar.1991@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the nature of the individual-level data and confidentiality and research ethics considerations, there is no plan to share the individual-level de-identified participant data after completion of the study.
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