Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

The effects of intermittent fasting diet alone or in combination with probiotic supplementation in comparison with calorie-restricted diet on anthropometric indices, lipid profile, glycemic status, hormonal parameters, inflammatory- and oxidative stress biomarkers in patients with polycystic ovary syndrome: a randomize clinical trial

Protocol summary

Study aim

The aim of the present study is to evaluate the effects of an intermittent fasting diet alone or in combination with probiotic supplementation in comparison with a calorie-restricted diet on anthropometric indices, lipid profile, glycemic status, hormonal parameters, inflammatory- and oxidative stress biomarkers in patients with polycystic ovary syndrome.

Design

This is a randomized, placebo-controlled, parallel-group clinical trial. Ninety participants will be randomly allocated to receive intermittent fasting with a probiotic (n = 30), an intermittent fasting diet with placebo (n = 30), or a calorie-restricted diet with a placebo (n = 30).

Settings and conduct

The study subjects will be selected according to the inclusion criteria from among the people suffering from polycystic ovary syndrome referring to the infertility center. Random assignment will be done by the use of the table of random numbers. The probiotic supplement and its placebo will be packed in similar boxes, and the patients will not be informed of the contents of the packages until the end of the study.

Participants/Inclusion and exclusion criteria

The cases will be enrolled in the study if they met these inclusion criteria: 1) age range between 18 and 40 years; 2) PCOS diagnosis based on the Rotterdam criteria for the first time; 3) body mass index between 25 and 35 kg/m2. Individuals with a history of cancer, cardiovascular disease, renal, hepatic, or using insulin or oral agents inducing insulin secretion will be excluded.

Intervention groups

Individuals will be randomly divided into three groups to receive intermittent fasting with a probiotic, intermittent fasting diet with a placebo, and calorie-restricted diet with a placebo.

Main outcome variables

Weight; Waist circumference; BMI; Fasting blood sugar; Insulin; Lipid profile; Inflammation; Oxidative stress markers; Hormonal markers; Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121110011421N5**
Registration date: **2022-10-03, 1401/07/11**
Registration timing: **prospective**

Last update: **2022-10-03, 1401/07/11**
Update count: **0**

Registration date

2022-10-03, 1401/07/11

Registrant information

Name

Kurosh Djafarian

Name of organization / entity

TUMS

Country

Iran (Islamic Republic of)

Phone

+98 88973901

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01
Expected recruitment end date
2023-09-23, 1402/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of intermittent fasting diet alone or in combination with probiotic supplementation in comparison with calorie-restricted diet on anthropometric indices, lipid profile, glycemic status, hormonal parameters, inflammatory- and oxidative stress biomarkers in patients with polycystic ovary syndrome: a randomize clinical trial

Public title
The effects of intermittent fasting diet alone or in combination with probiotic supplementation in comparison with calorie-restricted diet in patients with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of PCOS based on Rotterdam criteria for the first time Body mass index between 25 and 35 kg/m2 People who definitely eat breakfast (early breakfast) Have a smartphone Age range between 18 and 40 years
Exclusion criteria:
Smoking Alcohol drinking Taking OCP drugs, anti-androgens, metformin, lipid and blood pressure lowering drugs Pregnancy and breastfeeding Women who intend to become pregnant or take drugs such as chloramifel, letrozole and gonadotropin Menopausal women Antibiotic use in the last three months Consumption of probiotic products Night shift workers Intestinal malabsorption (history of bariatric surgery, inflammatory bowel disease, celiac disease) Inability to fast due to overnight medication Suffering from other diseases such as kidney disease, liver disease, cancer, heart disease and acute and chronic infectious diseases, type 1 and 2 diabetes, Cushing's disease, acromegaly, gigantism
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
A stratified randomized permuted block (with block size 6) will be generated by an independent bio-statistician. Subjects will be stratified according to BMI (between 25 and 30 and 30 and 35). Random assignment will be done by the use of a table of random numbers. The enrolling of participants, and assigning participants to the groups will be carried out by a trained nutritionist. Researchers will not be informed about the randomization process until the completion of data analyses (concealment).
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is not blinded in terms of diet but will be blinded in terms of supplements. The BioFem probiotic supplement and its placebo will be produced by Tak Gen Zist Company. All probiotic and its placebo supplements will provided by Tak Gen Zist Company in prepacked boxes numbered for each patient according to the randomization sequence.The probiotic supplement and its placebo will be in the same form package. The researcher and patients will not be aware of the pack's content until the end of the trial.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Ghods street., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
00982181633610
Approval date
2022-09-03, 1401/06/12
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.425

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Weight

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Digital scale

2

Description

HOMA- IR

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

HOMA- IR= insulin × glucose/405

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Colorimetric

2

Description

Insulin

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

3

Description

QUICKI; Quantitative insulin sensitivity check index

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

QUICKI= 1 / (log fasting blood glucose [mg/dl] + log fasting plasma insulin [µU / mL])

4

Description

HOMA-β; homeostatic model assessment of beta cell function

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

HOMA-β=360 × insulin/[glucose – 63]

5

Description

Total cholesterol

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzymatic method

6

Description

Triglyceride

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzymatic method

7

Description

Low density lipoprotein-cholestrol

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzymatic method

8

Description

High density lipoprotein-cholestrol

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzymatic method

9

Description

Testosterone

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

10

Description

SHBG; Sex hormone-binding globulin

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

11

Description

DHEA; Dehydroepiandrosterone

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

12

Description
Anti-Müllerian hormone
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

13

Description
Hirsutism
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Ferriman-Gallway score

14

Description
FAI; Free Androgen Index
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Calculation

15

Description
Total antioxidant capacity
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

16

Description
Total oxidant status
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

17

Description
Systolic blood pressure
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Sphygmomonometer

18

Description
Diastolic blood pressure
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Sphygmomonometer

19

Description
Waist Circumference
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Non-stretching tape measure

20

Description
Body Mass Index
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Dividing the weight into kilograms by squared height by meter

21

Description
Body fat percentage
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Bioimpedance

22

Description
Depression score
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

23

Description
Anxiety score
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

24

Description
Stress score
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

25

Description
Appetite
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement

Visual Analogue Scale

26

Description
Pittsburgh Sleep Quality Index (PSQI)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

27

Description
Scoring systems in acne
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Global acne grading system

28

Description
C-reactive protein
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

29

Description
Eating Behavior
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
The three factor eating questionnaire -R18

30

Description
Food Craving
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Food Craving Questionnaire

Intervention groups

1

Description
The first intervention group: Intermittent fasting diet (14:10) combined with probiotic supplement (BioFem) will receive for 8 weeks. The probiotic supplement will be manufactured by Takgene Zist Company (Tehran, Iran).
Category
Treatment - Other

2

Description
The second intervention group: will receive the intermittent fasting diet (14:10) along with the placebo supplement for 8 weeks. The placebo supplement will be manufactured by Takgene Zist Company (Tehran, Iran).
Category
Treatment - Other

3

Description
Control group: They will receive a calorie-restricted diet along with a placebo for 8 weeks. The placebo supplement will be manufactured by Takgene Zist Company (Tehran, Iran).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash Women Hospital
Full name of responsible person
Kurosh djafarian
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Shahid Baghdarnia Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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6th Floor, Central university building, Corner of Qods Ave., Keshavarz Blvd.
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Grant name
Vice Chancellor for Research, 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
Sepide Talebi
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Phd student in nutrition
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Master
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The collected deidentified for the primary outcome measure only will be shared.
When the data will become available and for how long

Starting 12 months after publication.

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

The data will provide for educational use.

From where data/document is obtainable

Kurosh djafarian kdjafarian@tums.ac.ir

What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

Comments