Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effect of Modified Alternate Day Fasting in comparison with energy restriction (Calorie Restriction) on anthropometric indices, glycemic markers, lipid parameters and hormone levels in people with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study was to evaluate the effect of modified intermittent fasting regimen in comparison with energy constraints on anthropometric indices, glycemic markers, lipid parameters and hormone levels in people with polycystic ovary syndrome.

Design

The clinical randomized trial, sham- controlled clinical trial with parallel groups

Settings and conduct

Subjects were recruited from the Infertility Center. after classification and matched according to age and BMI, these subjects were randomly divided into two groups. a group of subjects received Modified ADF and another group received Calorie Restriction for 8 weeks. At the beginning and the end of the study, outcomes were measured. The energy requirement of each person was calculated by Mifflin equation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with polycystic ovary syndrome, Age between 25- 45, High BMI, No weight change more and less than 5% for 3 months, no fasting for 3 months, Absence of diseases such as diabetes, Do not take drugs that affect glycemic index and lipid parameters, No smoking and alcohol, Intense physical inactivity, Failure to follow specific diets,. Exclusion criteria: Lack of cooperation of participants.

Intervention groups

For 2 weeks, the normal diet of individuals in both groups is observed and followed. In modified ADF group, subjects consumed very low- calorie diet (75% energy restriction) during the 3 fast days (Saturday, Monday, Wednesday) and then ate the diet that providing 125% of their energy needs on each feed day (3 days a week). In Friday subjects consumed ad libitum without limitation. In Calorie Restriction group, subjects consumed 75% energy needs in each day.

Main outcome variables

Weight, BMI, Waist circumference, Blood pressure, Fasting blood sugar, Total cholesterol, HDL, LDL, TG, FM, FFM, Fasting insulin, Prolactin, Testosterone, HOMA-IR, FSH, LH, TSH

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170221032698N2**
Registration date: **2021-09-20, 1400/06/29**
Registration timing: **prospective**

Last update: **2021-09-20, 1400/06/29**
Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Raihane Azizi

Name of organization / entity

University of Medical Science of Yazd

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01
Expected recruitment end date
2021-12-22, 1400/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Modified Alternate Day Fasting in comparison with energy restriction (Calorie Restriction) on anthropometric indices, glycemic markers, lipid parameters and hormone levels in people with polycystic ovary syndrome

Public title
The effect of low calorie diets on anthropometric, glycemic, cardiovascular and hormonal factors in people with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with polycystic ovary syndrome Age 25- 45 years 25 ≤ BMI ≤ 40 kg/m2 Body weight more than 5 kg has not changed during the last 3 months No fasting for 3 months prior to the beginning of the study Absence of diseases such as diabetes, cardiovascular, kidney, thyroid disorders, liver diseases, etc. Do not take medication, including drug that lower blood sugar, blood pressure and lipids. Also drugs that affect glycemic index and lipid parameters. No smoking and alcohol Intense physical inactivity Failure to follow specific diets People who, after explaining the work, are willing to cooperate and answer questions and perform experiments.
Exclusion criteria:
Lack of cooperation of participants in different stages of project implementation People who lose the conditions to enter the study
Age
From **25 years** old to **45 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
All participants were stratified for body mass index (BMI) and age, and were randomly assigned to ADF or CR group for 10 weeks. Randomization was performed using by random- generation software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Shahid Sadoughi University of Medical Sciences
Street address
Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi University of Medical Sciences, Yazd
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Yazd
Postal code
8916978477
Approval date
2021-06-30, 1400/04/09
Ethics committee reference number
IR.SSU.REC.1400.099

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
Body Weighy
Timepoint
Two times, before and after dietary intervention
Method of measurement
Weight with minimal coverage and without shoes using a SECA weight scale with an accuracy of 100 grams

2

Description
BMI
Timepoint
Two times, before and after dietary intervention
Method of measurement

Divide weight (kg) by height squared (m2)

3

Description
Waist circumference
Timepoint
Two times, before and after dietary intervention
Method of measurement
Between the lower margin of the last rib and the crown of the iliac bone at the level of the umbilicus and at the end of natural exhalation from the garment

4

Description
Blood pressure
Timepoint
Two times, before and after dietary intervention
Method of measurement
Blood pressure is measured using a mercury sphygmomanometer after sitting for 10 minutes.

5

Description
Fasting blood sugar
Timepoint
Two times, before and after dietary intervention
Method of measurement
In the FBS test, the patient should fast for 10-12 hours. Its normal amount varies according to the kit and test method. In the enzymatic method, FBS in normal adults is 110-70 mg / dl.

6

Description
Total cholesterol
Timepoint
Two times, before and after dietary intervention
Method of measurement
The amount (TC) is measured by enzymatic methods.

7

Description
HDL
Timepoint
Two times, before and after dietary intervention
Method of measurement
The amount (HDL) is measured by enzymatic methods.

8

Description
Triglyceride
Timepoint
Two times, before and after dietary intervention
Method of measurement
The amount (TG) is measured by enzymatic methods.

9

Description
LDL
Timepoint
Two times, before and after dietary intervention
Method of measurement
Serum LDL will also be calculated using the Friedwald equation.

10

Description
Fat Mass
Timepoint
Two times, before and after dietary intervention
Method of measurement
Body composition analyzer

11

Description
Fat Free Mass
Timepoint
Two times, before and after dietary intervention
Method of measurement
Body composition analyzer

12

Description
Fasting insulin
Timepoint
Two times, before and after dietary intervention
Method of measurement
fasting insulin was assayed using ELISA kits.

13

Description
HOMA- IR
Timepoint
Two times, before and after dietary intervention
Method of measurement
HOMA-IR = fasting insulin (μU/ml) × fasting blood sugar (mg/dl) / 405

14

Description
FSH
Timepoint
Two times, before and after dietary intervention
Method of measurement
FSH levels will be measured through the ELISA kit.

15

Description
LH
Timepoint
Two times, before and after dietary intervention
Method of measurement
LH levels will be measured through the ELISA kit

16

Description
TSH
Timepoint
Two times, before and after dietary intervention
Method of measurement
TSH levels will be measured through the ELISA kit

17

Description
testosterone
Timepoint
Two times, before and after dietary intervention
Method of measurement
testosterone levels will be measured through the ELISA kit

18

Description
Prolactin
Timepoint
Two times, before and after dietary intervention
Method of measurement
ICMA will be used to measure serum prolactin levels.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The normal diet of individuals is observed and followed for 2 weeks. Then, the ADF group consumed 25% of their energy on 3 days of the week (Saturday, Monday, Wednesday) for 8 weeks and then ate diet that providing 125% of their energy needs on each feed day (3 days a week). In Friday subjects consume ad libitum without limitation. These people received between 400 and 600 kcal of energy on fasting days. The feed and fast days began at midnight each day, and all fast day meals were consumed between 12.00 pm and 2.00 pm to ensure that each subject was undergoing the same duration of fasting. all food prepared in the home. Subjects were permitted to consume calorie- free foods (such as water, green tea, coffee without sugar (< 400 mg caffeine per day), non-starchy vegetable (such as lettuce, cucumber, green leaf, tomato) and sugar free gums on the fast day and were encouraged to drink plenty of water.
Category
Lifestyle

2

Description
Control group: The normal diet of individuals is observed and followed for 2 weeks. Then, in Calorie Restriction group, subjects consumed 75% energy needs in each day for 8 weeks and includes 3 main meals and 2 snacks. All subjects in two groups were required to prepare all of their meals at home. The baseline energy requirements for the subjects were assessed by Mifflin equation. Daily dietary carbohydrate, fat and protein accounted for 52, 30 and 18% of ingested energy, respectively.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Reyhaneh Azizi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
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Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi University of Medical Sciences, Yazd
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mmirzaei@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Reyhaneh azizi

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Others

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Diabetes Research and Treatment Center, Shahid Sadoughi Ave., Yazd, Iran

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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