

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

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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 $25 \leq \text{BMI} \leq 40 \text{ kg/m}^2$ 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

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Bahonar Sq., Shahid Sadoughi Ave., Shahid Sadoughi University of Medical Sciences, Yazd

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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

$\text{HOMA-IR} = \text{fasting insulin } (\mu\text{U/ml}) \times \text{fasting blood sugar } (\text{mg/dl}) / 405$

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

Full name of responsible person

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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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Person responsible for scientific inquiries

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Position

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Latest degree

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Person responsible for updating data

Contact

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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