

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of low free sugar diet on anthropometric parameters, lipid profile and glycemic control in women with polycystic ovarian syndrome

Protocol summary

Study aim

the effects of free sugar restricted diet on anthropometric parameters, lipid profile, glycemic control in women with polycystic ovary syndrome

Design

A clinical trial with a control group on 74 women with polycystic ovary syndrome (PCOS) randomized by Stratified Blocked Randomization.

Settings and conduct

Patients with PCOS referred to the women's clinic of Valiasr Hospital, who meet the inclusion criteria . After obtaining written consent, they will enter the study, they will be randomly divided into the group receiving the diet with low free sugar and the normal diet group along with nutritional recommendations for 12 weeks. At the beginning and end of the study, the anthropometric parameters will be measured and 5 cc of blood is taken from them after 10 to 12 hours of fasting.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with polycystic ovary syndrome according to the Rotterdam criteria, aged 18 and 45 years, less than 6 months have passed since the diagnosis of the disease, and more than 10% of their daily calories are from free sugars. Exclusion criteria: pregnancy and breastfeeding, following special diets or weight loss diets in the last three months, taking hormonal drugs, corticosteroids, omega-3 and spironolactone, suffering from uterine and ovarian cancers, liver diseases, suffering from kidney failure. and heart failure, infectious or inflammatory diseases, thyroid gland disorders, diabetes, hyperprolactinemia unwillingness to cooperate

Intervention groups

Patients in the intervention group (37 people) eat a diet with less than 3% of free sugar calories and in the control group (37 people) follow their usual diet along with dietary recommendations for 12 weeks.

Main outcome variables

fasting blood glucose (FBG) Serum insulin HOMA-IR

QUICK lipid profile Anthropometric parameters

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20230615058489N1**

Registration date: **2023-06-25, 1402/04/04**

Registration timing: **prospective**

Last update: **2023-06-25, 1402/04/04**

Update count: **0**

Registration date

2023-06-25, 1402/04/04

Registrant information

Name

Hajar Gholamshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low free sugar diet on anthropometric parameters, lipid profile and glycemic control in women with polycystic ovarian syndrome

Public title

the effect of low free sugar diet in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

willingness to participate in research Age 18-45 years BMI> 25 Having polycystic ovarian syndrom based on the diagnosis of gynecologist (According to Rotterdam criteria) Less than 6 months have passed since diagnosis People who get more than 10% of their calories from free sugars Absence of other diseases and chronic and acute disorders of women such as uterine and ovarian cancers Not suffering from liver diseases, suffering from kidney failure and heart failure, suffering from infectious or inflammatory diseases, suffering from thyroid gland disorders, diabetes, types of cancer, hyperprolactinemia Not pregnant or breastfeeding Non-adherence to special diets or weight loss diets in the last three months Not using hormonal drugs, corticosteroids, omega-3 and spironolactone

Exclusion criteria:

Unwillingness to continue cooperation Failure to follow the intervention diet for more than 2 days Starting a new diet other than the nutritional recommendations provided in the control group pregnancy Changing the medication regimen, physical activity during the intervention period

AgeFrom **18 years** old to **45 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **74****Randomization (investigator's opinion)**

Randomized

Randomization description

In order to randomly assign patients to two groups, stratified blocked randomization method is used based on BMI (overweight or obese). The size of the blocks is 4 blocks, two allocations to the intervention group (A) and two allocations to the control group (B) are considered. 6 permutations including AABB, ABAB, BBAA, BABA, ABBA, BAAB will be created. Finally, these permutations will be used for both BMI blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research ethic committee Islamic Azad University_ Science and research Branch

Street address

Science and Research Branch, Daneshgah Blvd, Simon Bulivar Blvd, Tehran

City

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Province

Tehran

Postal code

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Approval date

2023-06-10, 1402/03/20

Ethics committee reference number

IR.IAU.SRB.REC.1402.041

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**

Fasting Blood Glucose (FBG)

Timepoint

Beggining and after 12 weeks

Method of measurement

Enzymatic method

2**Description**

serum insulin

Timepoint

Beggining and after 12 weeks

Method of measurement

ELISA

3

Description

HOMA-IR

Timepoint

Beggining and after 12 weeks

Method of measurement

Calculate

4

Description

QUICKI

Timepoint

Beggining and after 12 weeks

Method of measurement

calculate

5

Description

Serum triglycerides

Timepoint

Beggining and after 12 weeks

Method of measurement

Enzymatic Method

6

Description

Total serum cholesterol

Timepoint

Beggining and after 12 weeks

Method of measurement

Enzymatic Method

7

Description

Serum LDL-C

Timepoint

Beggining and after 12 weeks

Method of measurement

Enzymatic Method

8

Description

Serum HDL-C

Timepoint

Beginning and after 12 weeks

Method of measurement

Enzymatic Method

9

Description

Weight

Timepoint

Beginning and after 12 weeks

Method of measurement

Scales

10

Description

Body Mass Index

Timepoint

Beginning and after 12 weeks

Method of measurement

Calculate

11

Description

Waist to hip ratio

Timepoint

Beginning and after 12 weeks

Method of measurement

Calculate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For 12 weeks, the low free sugar diet (less than 3% of calories are from free sugar) is provided along with the recommendations of a healthy diet and physical activity, and in order to follow the program, a food record is recorded every 2 weeks through A phone call is made.

Category

Treatment - Other

2

Description

Control group: food and physical activity recommendations / 12 weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Valiasr Hospital Women's Clinic

Full name of responsible person

Hajar GHolamshahi

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Valiasr Hospital, Valiasr Ave,Above Mirdamad Blvd
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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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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

1

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Asal Ataie Jafari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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