

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Aug 2026

Comparison of the effect of portfolio low-carbohydrate diet and the ketogenic diet on anthropometric indices, hormonal and lipid profiles in overweight or obese women with polycystic ovary syndrome

Protocol summary

Study aim

Determining the effect of low carbohydrate portfolio diet and ketogenic diet on anthropometric indices, hormonal and lipid profiles of overweight or obese women with polycystic ovary syndrome

Design

Two arms parallel-group randomized trial with a control group, phase 2 on 46 patients. The random block was used for randomization.

Settings and conduct

46 women with polycystic ovary syndrome referred to Motazadi medical center with the diagnosis of gynecologists, obstetrics and endocrinologists, if there are at least two factors based on the Rotterdam criteria, are diagnosed and selected from the following cases. People will be randomly divided into two groups: ketogenic diet (intervention) and low carbohydrate portfolio diet (control). There is no possibility of blinding for dietary presentation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female, Aged 18-40 years, Having Polycystic ovary syndrome according to Rotterdam criteria. Body mass index 25-39.9 kg/m², Desire to lose weight; Exclusion criteria: Pregnancy, Lactation, Following special or low-calorie diets for at least the last three months, Having diabetes, Having adrenal gland disorders, Having thyroid diseases, Taking effective drugs on carbohydrate or lipid metabolism, Use of oral contraceptive pills, Use of antiepileptic pills, Use of fish oil, Use of drugs to enhance fertility or weight loss, Having hypertension, Having cardiovascular diseases, Having anemia

Intervention groups

Patients in the intervention group will receive a ketogenic diet, which will have a high-fat content (70%) and low carbohydrate content (20%) Patients in the control group will receive a low-carbohydrate portfolio

diet, which consists of 40% of calories from carbohydrates, 20% from protein, and 40% from fat. The duration of the intervention will be 4 weeks

Main outcome variables

Total cholesterol, LDL cholesterol, Fasting blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200912048693N3**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **prospective**

Last update: **2022-12-23, 1401/10/02**

Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

Name

Amir Saber

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2009

Email address

amir.saber@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of portfolio low-carbohydrate diet and the ketogenic diet on anthropometric indices, hormonal and lipid profiles in overweight or obese women with polycystic ovary syndrome

Public title

Comparison of the effect of portfolio low-carbohydrate diet and the ketogenic diet in women with polycystic ovary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All women with PCOS that diagnosed by a gynecologist based on the Rotterdam criteria, which includes having at least 2 of the 3 listed symptoms 1) Oligomenorrhea or amenorrhea 2) Biochemical or clinical symptoms of increased androgen levels in the blood 3) Having polycystic ovaries in ultrasound. Having a body mass index of 25-39.9 kg/m² Having a desire to lose weight

Exclusion criteria:

Pregnancy Lactation Following special or low-calorie diets for at least the last three months Having diabetes Having adrenal gland disorders Having systematic or mental diseases Having thyroid diseases Taking drugs affecting carbohydrate or lipid metabolism Taking oral contraceptive pills Taking anti-epileptic pills Taking statins Fish oil consumption Use of fertility enhancing drugs or weight loss drugs Use of hormonal treatments or insulin sensitizing drugs in the last two months Having liver and kidney disease Having high blood pressure Having anemia Having severe respiratory diseases such as asthma and chronic inflammation of the bronchi Having cardiovascular diseases Having autoimmune diseases

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **46****Randomization (investigator's opinion)**

Randomized

Randomization description

The samples will be included in the study by random block method using 6 random blocks that will be created using the website <https://www.sealedenvelope.com>. The person who collects the information is unaware of the type of allocation of the samples to the study groups. The following items will be considered regarding the

implementation of the random allocation process: a) One English letter is assigned to each of the groups: A to the low carbohydrate portfolio diet group, B to the ketogenic diet group. b) A sequence will be created for a sample size of 46. c) For the concealment process of random allocation, 46 non-transparent envelopes and cards (as much as the total sample size) will be prepared. Inside each envelope, 6 cards will be placed in the order of the sequence in each block. The number of blocks will be written on each envelope and the name of the desired group will be written on each card.

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**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Faculty of Nutritional Sciences and Food Industry, next to Farabi hospital, Esar square, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6719851552

Approval date

2022-12-18, 1401/09/27

Ethics committee reference number

IR.KUMS.REC.1401.404

Health conditions studied**1****Description of health condition studied**

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Total cholesterol

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Direct enzymatic method

2

Description

LDL cholesterol

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Direct enzymatic method

3

Description

Fasting blood sugar

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Glucose oxidase assay

Secondary outcomes

1

Description

Weight

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Measure with a scale

2

Description

Body mass index

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Weight in kilograms divided by the square of height in
meters

3

Description

Insulin

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

4

Description

Testosterone

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

5

Description

Luteinizing hormone

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

6

Description

Follicle stimulation hormone

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

7

Description

Dehydroepiandrosterone

Timepoint

At the beginning of the study (before the intervention)
and at the end of the study

Method of measurement

Enzyme-Linked Immunosorbent Assay

Intervention groups

1

Description

Intervention group: ketogenic diet, in this group, the basic calorie amount of the participants is calculated through the formula of estimating the amount of energy consumed according to the amount of physical activity of them so that the total calories needed by the person are calculated. Then 500 kcal will be deducted from the diet offered to the person. The ketogenic diet will have a high-fat content (70%) and low carbohydrate (20%) which will cause the production of ketone bodies in the individual; Duration of intervention: 4 weeks

Category

Rehabilitation

2

Description

Control group: Low-carbohydrate portfolio diet, in this group, the basic calorie amount of the participants is calculated through the formula of estimating the amount of energy consumed according to the amount of physical activity of them so that the total calories needed by the

person are calculated. Then 500 kcal will be deducted from the diet offered to the person. The low-carbohydrate portfolio diet is a type of diet that consists of 40% of calories from carbohydrates, 20% from protein, and 40% from fat, emphasizing the consumption of four cholesterol-lowering substances, including vegetable protein, viscous fiber, nuts, and phytosterols. Duration of intervention: 4 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Motazedi Educational and Medical Center of Kermanshah University of Medical Sciences

Full name of responsible person

Amir Saber

Street address

Motazedi Clinic, Ferdowsi Square, Kermanshah

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amir.saber@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Cyrus Jalili

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Deputy of Research and Technology, Building No. 2, Shahid Beheshti Blvd.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Amir Saber

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Faculty of Nutrition Sciences and Food Industry, Next to Farabi hospital, Esar Square, Kermanshah

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Amir Saber

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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amir.saber@kums.ac.ir

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data relating to the primary and secondary outcomes will be shared

When the data will become available and for how long

Access starts 6 months after the results are published

To whom data/document is available

Researchers in academic and scientific institutions, as well as people in the industry, are allowed to access the data

Under which criteria data/document could be used

Anyone who request our data should provide a brief explanation of the purpose and method of their meta-analysis study. The applicant's request will be reviewed by the researchers and if all agree, the requested data will be sent to the applicant via email in the form of an Excel file. All of these steps will not take more than 10 days.

From where data/document is obtainable

Amir Saber, Assistant Professor, Kermanshah University of Medical Sciences, Faculty of Nutrition Sciences and Food Industry, Address: Faculty of Nutrition Sciences and Food Industry, Next to Farabi hospital, Esar Square, Kermanshah Postal code: 6719851552 Phone: 0098 83 37102008 Email: amir.saber@kums.ac.ir

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

After sending the request by the applicant and confirming the goals and method of the study by all project researchers, the data will be provided by email in less than 10 days.

Comments