

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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/m<sup>2</sup>, 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/m<sup>2</sup> 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

**Age**

From **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

**City**

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6719851552

**Phone**

+98 83 3710 2008

**Email**

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

**Street address**

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

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**Email**

cjalili@kums.ac.ir

**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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**Phone**

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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**

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**Email**

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**Person responsible for updating data****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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**Phone**

0098 37102008

**Email**

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**