Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 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
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Cyrus Jalili

Street address
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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

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

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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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Person responsible for updating data

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Position
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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