

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study of the effect of high protein-low carbohydrate weight loss diet with fennel supplement on androgens and anthropometric indices in overweight and obese women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study was to evaluate the effects of high-protein- low carbohydrates weight loss diet with fennel supplement on anthropometric factors, androgens in obese and overweight patients with polycystic ovary syndrome

Design

In this study, 64 patients are chosen who have inclusion criteria. participant were randomly allocated to four intervention groups and given code to each of theme.

Settings and conduct

A randomized double-blind clinical trial was conducted in obese and overweight patients with a polycystic ovary syndrome who referred to Imam Ali and a diabetes clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study, including polycystic ovary syndrome based on Rotterdam criteria and being overweight or obese (BMI greater than or equal to 25), 18-45 ages and willing to participate in this study; Exclusion criteria of this study are other causes of hyper androgenism and people with severe hirsutism, acne or severe hair loss, and history of hypersensitivity to fennel or any of its compounds. , Pregnancy and those who tend to be pregnant, have allergic asthma, seizures, liver and kidney disease (urea and creatinine above normal range), or cancer.

Intervention groups

The first group received high protein-low-carbohydrate weight loss diet with fennel capsule, the second group received high protein-low-carbohydrate weight loss diet with placebo, the third group received Standard weight loss diet with fennel capsule and fourth group received Standard weight loss diet with placebo

Main outcome variables

Total testosterone, SHBG, Weight, waist circumference, hip circumference

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120913010826N28**

Registration date: **2018-04-07, 1397/01/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-07, 1397/01/18**

Update count: **0**

Registration date

2018-04-07, 1397/01/18

Registrant information

Name

Azadeh Nadjarzadeh

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 202 2817

Email address

azadnajarzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-22, 1396/07/30

Expected recruitment end date

2018-10-21, 1397/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of high protein-low carbohydrate weight loss diet with fennel supplement on androgens and anthropometric indices in overweight and obese women with polycystic ovary syndrome

Public title

Effect of high protein-low carbohydrate weight loss diet with fennel supplement in women with polycystic ovary syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

polycystic ovary syndrome based on the Rotterdam criteria, at least two criteria of the three following criteria: 1) anovulation or oligo- ovulation or menstrual cycle less than 6 times in 12 months. 2) Clinical or biochemical increase in androgens, including the presence of acne, hirsutism, alopecia or serum levels of androgens . 3) Polycystic view with 12 or more follicles in each ovary with a diameter of between 3-2Myly meters or ovarian volume increased more than 11 cm overweight or obese (BMI greater than or equal to 25) aged 18-45 years willing to participate in this study

Exclusion criteria:

The other causes of hyperandrogenism, Congenital adrenal hyperplasia, Cushing, hypothyroidism, hyperprolactinemia, and Androgen-secreting tumors and those with hirsutism, acne or severe hair loss Allergy to anise or any of its components pregnant women and people who desire to pregnancy allergic asthma seizures liver and renal (urea and creatinine above the normal range) disease cancer

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals were randomly assigned to four intervention groups using a randomized table: 1-high proteine- low carohydrate diet weight loss diet with fennel, 2-high proteine- low carohydrate diet weight loss diet with placebo 3-standard weight loss diet with fennel, 4- standard weight loss diet with placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Prescribing supplement and placebo by a researcher without knowledge of its type, as well as taking it by the participants in the study without their knowledge. There is no possibility of blindness for the diet. In order to minimize bias in the intervention, one researcher randomly assigns random access to the patient in a randomized manner, without any knowledge of the patient's condition, and the other investigator who is associated with the patient, will place that person in the designated group.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd university of Medical Sciences

Street address

Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2017-07-17, 1396/04/26

Ethics committee reference number

ir.ssu.sph.rec.1396.88

2

Ethics committee

Name of ethics committee

Ethics committee of Yazd University of Sciences

Street address

آدرس خیابان Campus of Sadoughi University of Medical Sciences, Shohadaye Gomnam Blv, Yazd

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Province

Yazd

Postal code

8915173160

Approval date

2017-07-17, 1396/04/26

Ethics committee reference number

ir.ssu.sph.rec.1396.88

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

Total Testosterone

Timepoint

before and after 12 weeks treatment

Method of measurement

Using ELISA

2

Description

SHBG (Sex hormone-binding globulin)

Timepoint

before and after 12 weeks treatment

Method of measurement

Using ELISA

3

Description

weight

Timepoint

before and after 12 weeks treatment

Method of measurement

Scale

4

Description

waist circumference

Timepoint

before and after 12 weeks treatment

Method of measurement

Meter

5

Description

hip circumference

Timepoint

before and after 12 weeks treatment

Method of measurement

Meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Prescribe high protein- low carbohydrate weight loss diet with 2 fennel capsule per day

Category

Treatment - Drugs

2

Description

Intervention group 2: prescribe high protein-low carbohydrate weight loss diet with 2 placebo capsule per day

Category

Placebo

3

Description

Control group 1: prescribe Standard weight loss diet (The amount of energy needed by each individual will be calculated using an ideal weight of BMI 22 to 23 kg / m², and 500 calories will be deducted from the total energy required with 2 fennel capsule per day.

Category

Treatment - Drugs

4

Description

Control group 2: prescribe Standard weight loss diet with 2 placebo capsule per day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Dr. Azadeh Nadjarzadeh

Street address

Department of nutrition, school of public health, shahid sadoughi university of medical sciences, Yazd, Iran

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2

Recruitment center

Name of recruitment center

diabetes clinic

Full name of responsible person

Dr.Azadeh Najarzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Amir Hoshang Mehrparvar

Street address

یزد، میدان باهنر، دانشگاه علوم پزشکی شهید صدوقی یزد

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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

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

دانشگاه علوم پزشکی یزد

Full name of responsible person

Elham Hosseini Marnani

Position

Master Student of Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Fax**Email**

Elham_Hosseini1993@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Azadeh Nadjarzadeh

Position

Associate Professor, nutrition specialist

Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Master Student of Health Sciences in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

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Elham_Hosseini1993@yahoo.com

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data report will be shared after publishing the paper.

When the data will become available and for how long

Six months after publish

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Using for Meta-analysis

From where data/document is obtainable

Center nutrition, public health, university of medical
sciences yazd Tel: 009835 31492239 Email:
azadehnajarzadeh@gmail.com Azadenadjarzadeh

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

It will be sent two weeks after the receipt of the email
with the consent of the co-workers

Comments