Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of flaxseed on anthropometric indices and androgen levels in women with polycystic ovary syndrome

Protocol summary

Summary

This study is a clinical trial that will be designed to evaluate the effect of flaxseed on anthropometric indices and androgen levels in women with polycystic ovary syndrome . In this study after obtaining written consent from people participating in the study , the information that are required will be collected by filling out the general information questionnaire. Inclusion criteria are Polycystic ovary syndrome, being overweight or obese and aged 20 to 40 years,Exclusion criteria are pregnancy and lactation, using of hormonal or steroid drugs , history of gastrointestinal obstruction, inflammatory bowel disease,using of anti-platelet drug, and being sensitive to flax seeds,to assess dietary intakes of food 3-day questionnaire will be used.In this study, subjects will be divided into two groups by Using a table of random numbers.The first group will undergo weight loss diet with a daily intake of 15 grams of flaxseed and the second group will undergo weight loss diet with a daily intake of 15 grams of bread powder. Flaxseed and dry bread powder will be packaged and coding in completely similar packet. Researchers and patients, are not aware of the type supplements in the packet. At the beginning and end of the intervention period, anthropometric measurements and serum total testosterone, free testosterone and sex hormone-binding protein will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021110826N22**
Registration date: **2017-05-01, 1396/02/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

Name
Azadeh Nadjarzadeh
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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+98 912 202 2817
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Recruitment status

Recruitment complete

Funding source
Shahid Sadoughi University of Medical Sciences of Yazd

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-04-25, 1396/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of flaxseed on anthropometric indices and androgen levels in women with polycystic ovary syndrome

Public title

The effect of flaxseed on anthropometric indices and androgen levels in women with polycystic ovary syndrome

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Polycystic ovary syndrome (having at least two of the following: 1. anovulation or irregular ovulation symptoms 2. biochemical or clinical signs of hyperandrogenism 3. having small cysts in the ovaries), being overweight or obese (BMI greater than or equal to 25), aged 20 to 40 years and desire to collaborate on projects Exclusion criteria: pregnancy and lactation, using of hormonal or steroid drugs , history of gastrointestinal obstruction, inflammatory bowel disease,using of anti-platelet drug, and being sensitive to flax seeds.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics Committee of Shahid Sadoughi University of Medical Sciences of Yazd
Street address
School of health, shahid sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd, Alem Square,yazd
City
yazd
Postal code
Approval date
2017-02-05, 1395/11/17
Ethics committee reference number
IR.SSU.SPH.REC.1395.140

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Serum total testosterone
Timepoint
Before and after of each intervention
Method of measurement
Using ELISA

2

Description
Serum free testosterone
Timepoint
Before and after of each intervention
Method of measurement
Using ELISA

3

Description
Sex hormone binding globulin
Timepoint
Before and after of each intervention
Method of measurement
Using ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Group 1 consume 15 grams of powdered flaxseed daily for 12 weeks .
Category
Other

2

Description
Group 2 consume 15 grams of Bread powder daily for 12 weeks.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
ISFAHAN SHAHID BEHESHTI HOSBITAL

Full name of responsible person

Street address
shahid beheshti hospital, motahari st, isfahan

City
ISFAHAN

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research Shahid Sadoughi University of Medical Sciences and Health Services of Y

Full name of responsible person
امیرهوشنگ مهرپرور

Street address
School of health, shahid sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd, Alem Square,yazd

City
Yazd

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research Shahid Sadoughi University of Medical Sciences and Health Services of Y

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Msc student, Nutrition

Full name of responsible person
zahra heidari

Position
Yazd University of Medical Sciences

Other areas of specialty/work

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Yazd

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Person responsible for scientific inquiries

Contact

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PhD in Nutrition Sciences

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Person responsible for updating data

Contact

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Position
Msc student, Nutrition

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty