Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Sep 2026

Effect of flaxseed powder on levels of the glycemic indices, lipid Profile, inflammatory factors, adipocytokines and androgen profile in women with polycystic ovarian syndrome

Protocol summary

Study aim

Determination of the effect of flaxseed powder on levels of the glycemic indices, lipid Profile,inflammatory factors, adipocytokines and androgen profile in women with polycystic ovarian syndrome

Design

This is a randomized unblinded clinical trial with two parallel groups in Phase 3. In this research, 56 eligible patients referring to Polycystic ovarian syndrome were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This study will be conducted at the Jundishapur University of Medical Sciences in Ahwaz, and the diagnosis will be done at the specialized clinic of Golestan Hospital.In this study, after sampling and randomization, the intervention group daily received 3 grams of granule powder for 3 months.Both groups interventions and control receive recommendations for lifestyle modification.At the beginning and the end of the study, fasting blood samples will be taken from patients to measure lipid profiles, glycemic, testosterone, SHBG, IL-6, hs-CRP, leptin and adipontin.

Participants/Inclusion and exclusion criteria

Patients with polycystic ovary syndrome based on Rotterdam criteria Age 20-45 years Lack of heart disease, kidney disease, diabetes, thyroid, liver and cancer Not pregnant or pregnant. Lack of food allergy to flaxseed or other similar seeds such as sesame Failure to follow a weight loss program during the study

Intervention groups

women with polycystic ovary syndrome who receive 30 grams of flaxseed powder daily for 12 weeks.

Main outcome variables

Insulin resistance; Testosterone level; SHBG level; Leptin and Adiponectin levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120704010181N11**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1373 8255

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-21, 1396/08/30

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of flaxseed powder on levels of the glycemic indices, lipid Profile, inflammatory factors, adipocytokines and androgen profile in women with polycystic ovarian syndrome

Public title
The effect of flaxseed powder on the treatment of polycystic ovarian syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with polycystic ovarian syndrome BMI less than 35 kg/m2

Exclusion criteria:
Chronic diseases such as heart disease, diabetes, cancer, Thyroid gland disorders Following the weight loss program in the last 6 months. Taking any nutritional supplement Pregnancy

Age
From **20 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple (assigning a person to a particular group completely randomly) using a random number table

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 Ahwaz University of Medical Sciences

Street address
Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Approval date
2017-11-20, 1396/08/29

Ethics committee reference number
IR.AJUMS.REC.1396.619

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
Testosterone levels

Timepoint
At the beginning and end of the study

Method of measurement
Using ELISA Kit

2

Description
SHBG levels

Timepoint
At the beginning and end of the study

Method of measurement
Using ELISA Kit

3

Description
Serum levels of insulin

Timepoint
At the beginning and end of the study

Method of measurement
Using ELISA Kit

4

Description
Insulin resistance

Timepoint
At the beginning and end of the study

Method of measurement
Using HOMA-IR equation

5

Description
Insulin sensitivity

Timepoint
At the beginning and end of the study
Method of measurement
Using QUICKI equation

Secondary outcomes

1

Description
Grade Hirsutism Based on Freeman Galway questionnaire, Score more than 8
Timepoint
At the beginning and end of the study
Method of measurement
Based on Freeman Gallo's Questionnaire

2

Description
Menstrual Cycle
Timepoint
At the beginning and end of the study
Method of measurement
Based on individual interviews

Intervention groups

1

Description
Intervention group: Patients with polycystic ovarian syndrome who receive a daily dose of 30 grams of flaxseed for 12 weeks together with recommendations for lifestyle modification.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
کلینیک تخصصی بیمارستان گلستان
Full name of responsible person
محمد علی شیخی
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Nasrin Banaei
Position
Master of Student
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

it is not the objective of this study.

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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