

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the Effect of Flaxseed on Glycemic Indices, Lipid Profile, Hormones and Anthropometric Measurements on PCOS Patients

Protocol summary

Study aim

The aim of this study was to evaluate the effects of flax seed on patient with poly-cystic ovarian syndrome .

Design

Double blind randomized parallel clinical trial with two groups of control and intervention with a sample size of 84

Settings and conduct

select Poly-cystic Ovarian Syndrome patients based on inclusion and exclusion criteria that referred to zeinabieh clinic. then completed consent and other questionnaires for participants. finally patients settled on either groups based on randomisation. Patients will not be aware of the two groups being studied

Participants/Inclusion and exclusion criteria

Inclusion criteria : Diagnosis of Poly-cystic Ovarian Syndrome Based on Rotterdam Criteria By clinical practitioner, age 18 to 40 Exclusion criteria : Family history of breast, ovarian or uterine cancer, Pregnancy or lactation, Diabetes, thyroid disease or any systemic disease, Other disorders that lead to increased androgens in the blood, Menopause, Use of special drugs

Intervention groups

Intervention group: 30 grams of flax seed powder daily for 8 week in addition to weight loss diet and nutrition recommendations Control group: 30 grams of rice powder daily for 8 week in addition to weight loss diet and nutrition recommendations

Main outcome variables

Changes in glycemic indexes, changes in lipid factors, hormonal changes, weight change

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170916036204N8**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Najmeh Hejazi

Name of organization / entity

Shiraz University of Medical Sciences, Faculty of Nutrition and Food Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3725 1005

Email address

nhejazi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-20, 1398/10/30

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Effect of Flaxseed on Glycemic Indices, Lipid Profile, Hormones and Anthropometric Measurements on PCOS Patients

Public title

Evaluating the Effect of Flaxseed on PCOS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of Polycystic Ovarian Syndrome Based on Rotterdam Criteria By clinical practitioner

Exclusion criteria:

Family history of breast, ovarian or uterine cancer
Alcohol or drug use
Pregnancy or lactation
Use of anti-hypertension and lipid lowering drugs
Metformin use 6 months before enrollment and during the study
Diabetes, thyroid disease or any systemic disease (eg kidney, liver, digestive system, cardiovascular)
Other disorders that lead to increased androgens in the blood (such as Cushing's syndrome, hyper prolactinemia)
Menopause
Use of drugs that affect glucose metabolism

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with fixed block size of four

Blinding (investigator's opinion)

Double blinded

Blinding description

The sachets presented to the control group are filled with colored rice powder, with the same appearance and packaging as those given to intervention group. So the patients do not recognize which of the two groups they are in. Also, the physician and the data analyst are unaware of this.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Iran, Fars, Shiraz, Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.SUMS.REC.1398.711

Health conditions studied

1

Description of health condition studied

poly-cystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

At the beginning and the end of the study (after 8 weeks)

Method of measurement

FBS kit

2

Description

Insulin

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Insulin kit

Secondary outcomes

1

Description

Luteinizing Hormone

Timepoint

At the beginning and the end of the study (after 8 weeks)

Method of measurement

Luteinizing Hormone kit

2

Description

Follicle-Stimulating Hormone

Timepoint

At the beginning and the end of the study (after 8 weeks)

Method of measurement

Follicle-Stimulating Hormone kit

Intervention groups

1

Description

Intervention group: 30 grams of flax seed powder daily for 8 week in addition to weight loss diet and nutrition recommendations

Category

Treatment - Other

2

Description

Control group: 30 grams of rice powder daily for 8 week in addition to weight loss diet and nutrition recommendations

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zeinabieh clinic

Full name of responsible person

Zahra Moghdani

Street address

Zeinabieh clinic, Shiraz university of medical science

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Yunes Ghasemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Moghdani

Position

Master of Science in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Position

PHD in Nutrition Sciences, Assistant Professor of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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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

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