

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 adiponectin.

##### 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

Ahwaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1373 8255

##### Email address

haidari-f@ajums.ac.ir

##### 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/m<sup>2</sup>

#### 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

##### Street address

اتوبان گلستان

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

61357-33118

##### Phone

+98 61 3384 3001

##### Email

sheikhi-m@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badavi

##### Street address

Golestan Highway

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

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##### Phone

+98 61 3336 2414

##### Email

badavi-m@ajums.ac.ir

#### 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

Bachelor

##### 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

**Full name of responsible person**

Fatemeh Haidari

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

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**Email**

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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