Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determination of the effect of licorice extract on testosterone and Sex hormone binding globulin (SHBG), LH, FSH, Insulin, FBS, LDL, HDL, TG, Cholesterol, sleep quality, depression, and appetite in participants with polycystic ovary syndrome (PCOS) and overweight / obesity.

Protocol summary

Study aim

Determining the effect of licorice extract on sex hormone binding testosterone and globulin (SHBG) in patients with polycystic ovary syndrome (PCOS) with overweight or obesity

Design

randomized double blind controlled clinical trial, parallel group

Settings and conduct

Of the obese women referring to the Imam Ali Clinic in Yazd, 72 people will be selected and randomly divided into two groups. The participants and investigator will not be aware of the drugs and placebo. The amount of sex hormones will be measured before and after of the intervention. Intervention is parallel and is performed in 8 weeks.

Participants/Inclusion and exclusion criteria

1) Age 18-45 years 2) BMI 25-35 3) Polycystic ovary syndrome according to Rotterdam criteria 1)Blood pressure equal or more than 90/140 mmHg 2)Cardiovascular diseases with regular medication 3)Liver, kidney and thyroid disorders, diabetes 4)Smoking 5)Taking multi vitamin-mineral supplements 6)Antioxidant and herbal treatments during the previous 3 months 7)Pregnancy and lactation 8)Consumption of licorice more than 300 gr per week 9)hereditary adrenal hyperplasia, Cushing's syndrome, hyperprolactinemia and thyroid dysfunction (hypothyroidism) or androgen-secreting tumors 10)history of allergy to licorice or any of its compounds 11)The study did not include patients taking estrogen or progesterone, but those who had previously been treated with metformin continued to receive it. Moreover, the patients were not included if they had taken new drugs within two month before and during the study.

Intervention groups

Intervention: capsule containing 500 mg licorice extract three times daily Control: Placebo capsule containing Corn starch three times daily

Main outcome variables

Serum testosterone level; Serum SHBG level; Anthropometric measurements (height, weight, BMI, waist circumference, hip circumference, waist to hip ratio); Body composition.

General information

Reason for update

Some essential data were omitted due to oversight during the initial registration, so this update has been made to complete them.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200922048802N2**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **retrospective**

Last update: **2025-08-25, 1404/06/03**
Update count: **2**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Hadis Hooshmandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9100

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hadis.july.1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-11-29, 1399/09/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determination of the effect of licorice extract on testosterone and Sex hormone binding globulin (SHBG), LH, FSH, Insulin, FBS, LDL, HDL, TG, Cholesterol, sleep quality, depression, and appetite in participants with polycystic ovary syndrome (PCOS) and overweight / obesity.

Public title
Determination of the effect of licorice on Sex hormone, insulin and fasting blood sugar, blood lipids, depression, sleep quality and appetite in participants with polycystic ovary syndrome (PCOS) and overweight / obesity.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 45 BMI 25-35 kg/m2 Polycystic ovary syndrome based on Rotterdam criteria

Exclusion criteria:
Blood pressure equal or than 90/140 mmHg Cardiovascular diseases with regular drug use, liver, kidney and thyroid disorders, diabetes Taking multi vitamin-mineral supplements Smoking Antioxidant and herbal treatments during the last 3 months Pregnancy and lactation Consumption of licorice more than 300 grams per week Hyper androgenism includes hereditary adrenal hyperplasia, Cushing's syndrome, hyperprolactinemia, and hypothyroidism or androgen-secreting tumors History of allergy to licorice or any of its components

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: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: Simple Random unit: Individual Tool: Randomized Tables A balanced block method is used to allocate concealment so that the number of samples assigned to each of the groups is equal.

Blinding (investigator's opinion)
Double blinded

Blinding description
Supplements of licorice and placebo in the same capsules in terms of size, color and shape Encodes A and B on supplements and placebo

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 Yazd

Street address
School of health, Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd., Alem Sq.

City
Yazd

Province
Yazd

Postal code
8915173160

Approval date
2019-02-18, 1397/11/29

Ethics committee reference number
IR.SSU.SPH.REC.1397.152

Health conditions studied

1

Description of health condition studied
Polycystic ovarian syndrome

ICD-10 code
E28.2

ICD-10 code description
Polycystic ovarian syndrome

2

Description of health condition studied
Overweight and obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Serum testosterone level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
ELISA Kit

Secondary outcomes

1

Description
Serum SHBG level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
ELISA Kit

2

Description
Serum FSH level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
ELISA Kit

3

Description
Serum LH level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
ELISA Kit

4

Description
Serum insulin level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
ELISA Kit

5

Description
Serum FBS level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Biochemical analysis

6

Description
Serum LDL level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Biochemical analysis

7

Description
Serum HDL level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Biochemical analysis

8

Description
Serum TG level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Biochemical analysis

9

Description
Serum Cholesterol level
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Biochemical analysis

10

Description
BDI questionnaire
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Likert scale

11

Description
Pittsburgh Sleep Quality Index (PSQI)
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Likert scale

12

Description
The Council on Nutrition Appetite Questionnaire (CNAQ)
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Likert scale

13

Description
Body composition
Timepoint
at the beginning and end of 8-weeks intervention period

Method of measurement
Body analyzer

14

Description
Anthropometric measurements (height, weight, BMI, waist circumference, hip circumference, abdominal / hip ratio)
Timepoint
at the beginning and end of 8-weeks intervention period
Method of measurement
Body analyzer

Intervention groups

1

Description
People in this group will recieve three 500 mg capsules of licorice daily for 8 weeks.
Category
Treatment - Drugs

2

Description
Control group: People in this group will recieve three 500 mg capsules of placebo daily for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali clinic
Full name of responsible person
Hadis Hooshmandi
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Yazd University of Medical Sciences
Full name of responsible person

Hadis Hooshmandi
Position
Master student
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Person responsible for updating data

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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available