Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A randomized clinical trial to compare the effectiveness of oral contraceptives containing levonorgestrel, desogestrel, cyproterone acetate, and drospirenone on levels of adipokines, and adiposity indices in women with polycystic ovary syndrome.

Protocol summary

Study aim

To compare the effects of oral contraceptives containing levonorgestrel (LNG), desogestrel (DSG), Cyproterone Acetate (CPA), and drospirenone on serum adipokines including adiponectin, leptin and resistin in patients with polycystic ovarian syndrome (PCOS).

Design

This study is a randomized single blinded parallel clinical trial. Sample size is estimated as 80 person. This clinical trial is placed in phase 3 of clinical trials.

Settings and conduct

This randomized clinical trial will be done in the Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Present study will be done single-blind in which outcome assessor will be kept blind and won't be aware of the type of drug that the patients will receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: presence of diagnostic criteria for polycystic ovary syndrome based on the Androgen Excess and PCOS Society (AES); ages 18 to 45 years. Exclusion criteria: Pregnancy; Use of hormone drugs, anti-androgens and insulin sensitizers for at least three months; Smoking; Obesity; Chronic medical disorders; Serious side effects such as thrombosis.

Intervention groups

Intervention Group 1: Oral contraceptives (OCs) containing Levonorgestrel. Intervention Group 2: OCs containing Desogestrel. Intervention Group 3: OCs containing Cyproterone Acetate. Intervention Group 4: OCs containing Drospirenone.

Main outcome variables

Adiponectin; leptin; resistin.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080929001281N3**
Registration date: **2020-03-26, 1399/01/07**
Registration timing: **retrospective**

Last update: **2020-03-26, 1399/01/07**
Update count: **0**

Registration date

2020-03-26, 1399/01/07

Registrant information

Name
Fahimeh Ramezani Tehrani
Name of organization / entity
Research Institute for Endocrine Sciences
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+98 21 2243 2500
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-24, 1398/03/03

Expected recruitment end date

2019-09-11, 1398/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A randomized clinical trial to compare the effectiveness of oral contraceptives containing levonorgestrel, desogestrel, cyproterone acetate, and drospirenone on levels of adipokines, and adiposity indices in women with polycystic ovary syndrome.

Public title
Effect of oral contraceptives on levels of adipokines, and adiposity indices in women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Existence of diagnostic criteria for polycystic ovary syndrome based on Androgen Excess and PCOS Society (AES) Age range: 18 to 45 years
Exclusion criteria:
Pregnancy Use of hormonal; anti-androgen or insulin sensitizer drugs for at least 3 months before the study Detection of severe hypertension; chronic disease; recent surgery or diagnosis of cancer Smoking Obesity Appearing the serious side effects such as thrombosis

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
A blocking or stratification random allocation (block size = 4), using a computer-based random number generator will be prepared to assign participants to treatment groups. The randomization sequence will be prepared before the trial, initiated by an independent statistician.

Blinding (investigator's opinion)
Single blinded

Blinding description
Both the clinical examiner and data analyst are blinded to the intervention each patient receives during the trial. For this purpose, before beginning the study, a person outside the research team who knew the interventions, assigned patients to treatment groups. Hence, only this person was aware of the treatment in each group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences.
Street address
Research Institute for Endocrine Sciences, Shahid Aarabi street, Yaman street, Velenjac
City
تهران
Province
Tehran
Postal code
1985717413

Approval date
2018-08-14, 1397/05/23

Ethics committee reference number
IR.SBMU.ENDOCRINE.REC.1397.055

Health conditions studied

1

Description of health condition studied
Reproductive health.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Serum levels of adiponectin

Timepoint
baseline, 6th month

Method of measurement
Assessment of this parameter will be done using Human ELISA kites.

2

Description
Serum levels of leptin

Timepoint
baseline, 6th month

Method of measurement
Assessment of this parameter will be done using Human ELISA kites.

3

Description
Serum levels of resistin

Timepoint

baseline, 6th month

Method of measurement

Assessment of this parameter will be done using Human ELISA kites.

Secondary outcomes

1

Description

Blood pressure

Timepoint

Baseline, 6th month

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention group 1: Oral contraceptives containing Ethinyl estradiol (EE) 30 µg + levonorgestrel 0.15 mg (daily for 21 days and then 7 days withdrawal) made by Iran Hormone company, Iran.

Category

Treatment - Drugs

2

Description

Intervention group 2: oral contraceptives containing Ethinyl estradiol (EE) 30 µg + Desogestrel 150 µg (daily for 21 days and then 7 days withdrawal) made by Iran Hormone company, Iran.

Category

Treatment - Drugs

3

Description

Intervention group 3: oral contraceptives containing Ethinyl estradiol (EE) 35 µg + Cyproterone acetate (CPA) 2 mg (daily for 21 days and then 7 days withdrawal) made by Iran Hormone company, Iran.

Category

Treatment - Drugs

4

Description

Intervention group 4: oral contraceptives containing Ethinyl estradiol (EE) 30 µg + Drospirenone (DRSP) 3 mg (daily for 21 days and then 7 days withdrawal) made by Iran Hormone company, Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine out-patients clinic, Research Institute for Endocrine Sciences (RIES), Shahid Beheshti Uni

Full name of responsible person

Fahimeh Ramezani Tehrani

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No.24, Aarabi street, Yaman street, Velenjak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mina Amiri

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After completion of the study, part of the data, such as information about the main outcomes will be shared.

When the data will become available and for how long
Starting availability of data is 6 months after publishing the results.

To whom data/document is available
The data of this study will be available to all medical science researchers.

Under which criteria data/document could be used
Researchers are only permitted to use the above study information as descriptive analysis or as part of a meta-analysis.

From where data/document is obtainable
Applicants can contact Dr. Mina Amiri, Academic Member of the University of Medical Sciences, through the following address, contact number and email: Address: No 24, Institute of Endocrinology and Metabolism, Aarabi street, Yemen street, Velenjak. Phone: 00982122432569 Postcode: 1985717413 Email: mina_amiri_p@yahoo.com

What processes are involved for a request to access data/document
1- Submit a request to access the data file by email 2. Submission of a formal application form for the relevant research project and the need for the above study data

by the applicants: This form should only be issued through accredited research bodies. 3- Applicant's visit to Shahid Beheshti Institute of Endocrinology and Metabolism Research Institute to complete consent form to comply with ethical obligations required to use data 4- Investigating the Applicants' Application in the Scientific Committee of the Endocrinology Institute and Deciding to Submit Data as Non-Identifiable Study Participants (Maximum Within One Month) 5- Send study data to researcher's email 6. Monitor how data is used

Comments

Not comment.