Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

A Randomized cross-over clinical trial to assess the effectiveness of oral contraceptives including Contrasmine, Etisterone and Desoceptive with Ovustop-L (LD) on clinical, biochemical and metabolic findings, and quality of life in women with polycystic ovary syndrome.

Protocol summary

Summary

Oral contraceptives (OC) are the most common treatment for patients with polycystic ovary syndrome (PCOS) who do not seek pregnancy. Some studies have raised concern regarding the potential adverse cardiovascular and metabolic effects of OC in women with PCOS. Despite claims of better efficacy and fewer side effects the newer contraceptive compounds than Ovustop-L (LD), there are no strong clinical trials to confirm this effects. The aim of this randomized cross-over trial clinical was to compare the effectiveness of oral contraceptives including Contrasmine, Etisterone and Desoceptive with Ovustop-L (LD) on clinical, biochemical and metabolic findings, and quality of life in women with polycystic ovary syndrome. Sampling method will be convenience or continues. The examinations and laboratory tests will be done in the Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, Iran. Patients diagnosed based on Androgen Excess and PCOS Society (AES) criteria will be studied. In the present study, we will have 6 arms or group treatments that will be randomly assigned to each of the groups. Each patient will alternately be treated with Ovustop-L (LD) for a six-month period and a six month period with one of the other types of contraceptive treatment. A wash-out a period of 6 weeks will be considered between the two treatments. Outcomes will be evaluated before and after each treatment. Outcomes measured will be included clinical, hormonal and metabolic profiles and quality of life.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702071281N2**
Registration date: **2017-02-21, 1395/12/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-21, 1395/12/03

Registrant information

Name

Fahimeh Ramezani Tehrani

Name of organization / entity

Research Institute for Endocrine Sciences

Country

Iran (Islamic Republic of)

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+98 21 2243 2500

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ramezani@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A Randomized cross-over clinical trial to assess the effectiveness of oral contraceptives including Contrasmine, Etisterone and Desoceptive with Ovustop-L (LD) on clinical, biochemical and metabolic findings, and quality of life in women with polycystic ovary syndrome.

Public title
Comparison of oral contraceptives including Contrasmine, Etisterone and Desoceptive with Ovustop-L (LD) on clinical, biochemical and metabolic findings, and quality of life in women with polycystic ovary syndrome.

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: Existent of diagnostic criteria for polycystic ovary syndrome based on Androgen Excess and PCOS Society (AES), Lack of pregnancy diagnosis and tendency to it for a year or more, lack of using hormonal, anti-androgens or sensitizers drugs at least 3 months before the study, Failure to detect other causes of hyperandrogenism, Not having chronic medical conditions, high and severe blood pressure, recent surgery or known cancer, 6- Not smoking and non-obesity. Exclusion criteria: Not adherence to prescribed medications for more than two months, detection of chronic medical disorders, Appearing the serious effects such as thrombosis contraceptive.

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Crossover

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, Tehran, I

Street address
24 Parvaneh, Yaman Street, Velenjak, P.O.Box:19395-4763 Tehran, Iran

City
Tehran

Postal code

Approval date
2016-06-28, 1395/04/08

Ethics committee reference number
IR.SbMU.ENDOCRINE.REC.1395.194

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Free Androgen Index (FAI)

Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)

Method of measurement
According to the formula of total testosterone (nmol/ L)) x 100 /sex hormone-binding globulin)

Secondary outcomes

1

Description
Hirsutism

Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)

Method of measurement
Ferriman- Galwey scoring system

2

Description
Body mass index (BMI)

Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)

Method of measurement
kg/m2

3

Description
Acne
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Wang criteria

4

Description
Alopecia
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Ludwig criteria

5

Description
menstruation cycles pattern
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
questionnaire

6

Description
Insulin resistance
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Electrochemilumniscen immuno assay

7

Description
Fasting blood sugar (FBS)
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Enzymatic colorimetric

8

Description
(TG) triglyceride
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Calorimetric

9

Description
Total Cholesterol
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Calorimetric

10

Description
total testosterone (TT)
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
enzyme immunoassay

11

Description
Dehydroepiandrosterone sulfat
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
enzyme immunoassay

12

Description
Sex hormone-binding globulin (SHBG)
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months after second treatment, 6 months after second treatment)
Method of measurement
Immunoradiometric assay

13

Description
quality of life
Timepoint
(Before treatment, 3 months after first treatment, 6 months after first treatment, after wash-out, 3 months

after second treatment, 6 months after second treatment)

Method of measurement

Likert rating lifestyle questionnaire

Intervention groups

1

Description

A. Outcome measurement, 6 months of treatment with Ovustop-L, outcome measurement in the end of third and six months of treatment, a washout period for 6 weeks, Outcome measurement, the second treatment with Contrasmine for 6 months, outcome measurement in the end of third and six months of treatment.

Category

Treatment - Drugs

2

Description

B. Outcome measurement, 6 months of treatment with Contrasmine, outcome measurement in the end of third and six months of treatment, a washout period for 6 weeks, Outcome measurement, the second treatment with Ovustop-L for 6 months, outcome measurement in the end of third and six months of treatment.

Category

Treatment - Drugs

3

Description

C. Outcome measurement, 6 months of treatment with Ovustop-L, outcome measurement in the end of third and six months of treatment, a washout period for 6 weeks, Outcome measurement, the second treatment with Etisterone for 6 months, outcome measurement in the end of third and six months of treatment.

Category

Treatment - Drugs

4

Description

D. Outcome measurement, 6 months of treatment with Etisterone, outcome measurement in the end of third and six months of treatment, a washout period for 6 weeks, Outcome measurement, the second treatment with Ovustop-L for 6 months, outcome measurement in the end of third and six months of treatment.

Category

Treatment - Drugs

5

Description

E. Outcome measurement, 6 months of treatment with Ovustop-L, outcome measurement in the end of third and six months of treatment, a washout period for 6 weeks, Outcome measurement, the second treatment with Desoceptive for 6 months, outcome measurement in the end of third and six months of treatment.

Category

Treatment - Drugs

6

Description

F. Outcome measurement, 6 months of treatment with Desoceptive, outcome measurement in the end of third and six months of treatment, a washout period for 6 weeks, Outcome measurement, the second treatment with Ovustop-L for 6 months, outcome measurement in the end of third and six months of treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences,

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

(Health Houses (district 10

Full name of responsible person

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

(Health Houses (district 16

Full name of responsible person

Street address

City

Tehran

4

Recruitment center

Name of recruitment center

Health Houses (district 2)

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, I

Full name of responsible person
Fahimeh Ramezani Tehrani

Street address
24 Parvaneh, Yaman Street, Velenjak, P.O.Box:19395-4763, Tehran Iran.f

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences, Tehran, I

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Reproductive Endocrinology Research Center Research Institute for Endocrine Sciences ShahidBeheshti

Full name of responsible person
Fahimeh Ramezani Tehrani

Position
Professor

Other areas of specialty/work

Street address
24 Parvaneh, Yaman Street, Velenjak, P.O.Box:19395-4763 Tehran Tehran Iran

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty