

# 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)

##### Phone

+98 21 2243 2500

##### Email address

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: Existence 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/m<sup>2</sup>

### **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**

Electrochemiluminescence 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

**City**

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ramezani@endocrine.ac.ir

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Reproductive Endocrinology Research Center  
Research Institute for Endocrine Sciences Shahid Beheshti

**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

**City**

Tehran

**Postal code****Phone**

+98 21 2243 2500

**Fax****Email**

ramezani@endocrine.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Reproductive Endocrinology Research Center  
Research Institute for Endocrine Sciences Shahid Beheshti

**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

**City**

Tehran

**Postal code****Phone**

+98 21 2243 2500

**Fax****Email****Web page address**

### 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*