

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Relation between androgen hormone with sexual function in women use LD attending in selected Health centers of shiraz university of medical sciences in 2012-2013

#### Protocol summary

##### Summary

The objective of this prospective study is to consider relation between androgen hormone with sexual function in women use low-dose oral contraceptive (OC) containing 30 µg ethinylestradiol and 150 µg Levonorgestrel (LD). Eighty-nine married, healthy volunteers (age range, 18-35 years), having regular menstrual cycles participated in the study that have earned scores 28 or more of Female sexual function index (FSFI). Sexual function and androgen level was assessed by using the (FSFI) questionnaire and blood test at baseline, and at 3 months of pill use. If we will have sexual function disorder after pill use, we can offer another prospective method for couple that has no effect on sexual activity.

#### General information

##### Acronym

low dose contraceptive pill

##### IRCT registration information

IRCT registration number: **IRCT2013070213846N1**

Registration date: **2013-09-22, 1392/06/31**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-09-22, 1392/06/31

##### Registrant information

###### Name

Elham Sheikhan Shamsabadi

###### Name of organization / entity

Fatemeh (PBUH) College of Nursing and Midwifery  
Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1235 2559

###### Email address

sheikhan@sums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Research office of Shiraz University Of Medical Sciences

###### Expected recruitment start date

2013-08-12, 1392/05/21

###### Expected recruitment end date

2014-01-11, 1392/10/21

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Relation between androgen hormone with sexual function in women use LD attending in selected Health centers of shiraz university of medical sciences in 2012-2013

###### Public title

Relation between androgen hormone with sexual function in women use LD

###### Purpose

Health service research

###### Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate; married woman with age between 18-35 years old; having score 28 or more of Female Sexual Function Index; not pregnant; not having breast feeding; no history of heart disease and vascular disease (the patient's medical records); no history of uncontrolled hypertension and

hypotension; no history of liver dysfunction; not taking any medications that affect sexual function (specially common antidepressant); not having migraine and ulcer; don't use alcohol and cigarette; not sexual function disorder; regular menstruation. Exclusion criteria : taking hormone pills particularly OCP; taking alcohol or tobacco; history of active peptic ulcer disease ; history of headaches including migraines; history of dyspareunia or vaginismus.

#### **Age**

From **18 years** old to **35 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **89**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **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**

Shiraz University of Medical Sciences

##### **Street address**

Central department of Shiraz University of Medical Sciences, Zand Street, Shiraz

##### **City**

Shiraz

##### **Postal code**

##### **Approval date**

2013-08-11, 1392/05/20

##### **Ethics committee reference number**

CT-92-6661

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

female sexual dysfunction

##### **ICD-10 code**

F50-F59

### **ICD-10 code description**

Behavioural syndromes associated with physiological disturbances and physical factors

### **Primary outcomes**

#### **1**

##### **Description**

Female sexual dysfunction

##### **Timepoint**

At the start of intervention- After 3 months of intervention

##### **Method of measurement**

Female Sexual Function Index Questionnaire

### **Secondary outcomes**

#### **1**

##### **Description**

Improvement of sexual function

##### **Timepoint**

At the start of intervention- After 3 months of intervention

##### **Method of measurement**

Female Sexual Function Index Questionnaire

### **Intervention groups**

#### **1**

##### **Description**

Intervention with oral contraceptive(low dose) for 3 month /daily

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### **1**

##### **Recruitment center**

##### **Name of recruitment center**

Hazrate Abolfazl clinic

##### **Full name of responsible person**

Khadije Abdali

##### **Street address**

20 meter of emam khomeini ,rahmat bolovar,shiraz

##### **City**

Shiraz

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for Research, Shiraz University of Medical Sciences

##### **Full name of responsible person**

Dr. Gholam Reza Hatam

**Street address**

7th Flat, Central department of Shiraz University of Medical Sciences, Zand Street, Shiraz

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for Research, Shiraz University of Medical Sciences

**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**

Fatemeh College of Nursing And Midwifery, Shiraz University of Medical Sciences

**Full name of responsible person**

Khadije Abdali

**Position**

Faculty Member, MSc in Midwifery

**Other areas of specialty/work**

**Street address**

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

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Faculty Member, MSc in Midwifery

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**Person responsible for updating data**

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Fatemeh (PBUH) College of Nursing and Midwifery Shiraz University of Medical Sciences

**Full name of responsible person**

Elham Sheikhan Shamsabadi

**Position**

Student, MSc in Midwifery

**Other areas of specialty/work**

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**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*