Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 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 mensturation. Exclusion criteria : taking hormone pills particulary OCP; taking alchohl or tobacco; history of active peptic ulcer disease ; history of headaches including migraines; history of dysparunia 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

Namazi Square, Shiraz

City

Shiraz

Postal code

1311971936

Phone

+98 71 1647 4254

Fax

Email

abdalikh@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemeh (PBUH) 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

Namazi square, Shiraz

City

Shiraz

Postal code

1311971936

Phone

+98 71 1647 4252

Fax

Email

abdalikh@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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

Street address

Namazi square, Shiraz

City

Shiraz

Postal code

1311971936

Phone

+98 71 1647 4254

Fax

Email

sheikhan@sums.ac.ir

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