Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of Oral Contraceptive LD and Vitex on improvement clinical and paraclinical parameters of Polycystic ovarian syndrome (PCOS): a double blind randomized controlled clinical trial

Protocol summary

Summary

The aim of this randomized controlled trial (double blind) is comparing the effect of Oral Contraceptive LD and Vitex on improving clinical and para-clinical parameters of Polycystic ovarian syndrome (PCOS). 80 women aged 18 to 45 years old with PCOS will be recruited in the study. This study will be conducted at Alzahara hospital and Clinics affiliated to Tabriz University of Medical Sciences. Eligible women will be selected through convenience sampling and will be randomly assigned into 2 groups involving 40 subjects using permuted block randomization with allocation ratio of 1:1. A person from research team not involved in the recruitment and assigning participants will generate allocation sequence using a computerized program. Opaque sealed sequentially numbered envelops will be used for allocation concealment. Intervention group will receive Vitex agnus tablet two pills daily for three cycles of 28 days and control group will receive LD tablet one pill daily for first 21 days of each cycle through three cycles of 28 days. The last seven tablets in LD group contain placebo. Main outcome measure is menstrual cycle length which will be evaluated by calendar one , two, and three months after the intervention. Secondary outcomes include Serum levels of dehydroepiandrosterone sulfate, free testosterone and prolactin that will be assessed by Enzyme-linked immunosorbent assay (ELISA) before the intervention and three months after intervention.The researcher and the participants will be blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306116709N13**
Registration date: **2014-03-02, 1392/12/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-03-02, 1392/12/11

Registrant information

Name
Mahnaz Shahnazi
Name of organization / entity
Tabriz University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 41 1479 6770
Email address
mshahnazi@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research deputy of Tabriz university of medical sciences

Expected recruitment start date

2014-01-10, 1392/10/20

Expected recruitment end date

2014-06-30, 1393/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Oral Contraceptive LD and Vitex on improvement clinical and paraclinical parameters of Polycystic ovarian syndrome (PCOS): a double blind

randomized controlled clinical trial

Public title
Comparing the effect of Oral Contraceptive LD and Vitex to treat Polycystic ovarian syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: oligomenorrhea or amenorrhea (menstrual intervals longer than 35 days or no menstruation in the last three months); polycystic ovarian confirmed by ultrasound; age 45-18 years; willingness to participate in the study; Body mass index between 18 and 35. Exclusion criteria: having other androgenic disorders such as adrenal hyperplasia or androgen-producing tumors; contraindications of oral contraceptive LD including: smokers over 35 years, active liver diseases, systolic blood pressure equal to or above 140 mm Hg and diastolic equal to or above 90 mm Hg , diabetes for more than 20 years, gallbladder diseases, history of stroke, blood clots in the legs or lungs, heart attack and other cardiovascular problems, breast cancer, migraine with aura,... ; thyroid diseases; cushing's syndrome; currently taking oral contraceptives or other hormonal treatments; pregnancy; breastfeeding; history of surgery on one or both ovaries; taking dopamine antagonist drugs such Thioridazine, Promazine, Metoclopramide, Hydroxyzine, etc
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz university of Medical Sciences
Street address
Golgasht Street, Tabriz
City
Tabriz
Postal code
118-51665
Approval date
2013-12-09, 1392/09/18
Ethics committee reference number
92151

Health conditions studied

1

Description of health condition studied
polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
Menstrual cycle length
Timepoint
One month, two months, three months after the intervention
Method of measurement
Calendar

Secondary outcomes

1

Description
Serum Dehydroepiandrosterone sulfate level
Timepoint
Before the intervention and three months after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

2

Description
Serum free testosterone level
Timepoint
Before the intervention and three months after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA)

3

Description
Serum prolactin levels
Timepoint
Before the intervention and three months after

intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

Intervention groups

1

Description

Intervention group: Vitex agnus tablet, containing standardized pure extract of Vitex agnus fruits with 2.1 to 3.3 mg acubin, two pills daily for three cycles of 28 days .

Category

Treatment - Drugs

2

Description

Control group: LD tablet, containing 30 mcg ethinyl estradiol and 150 mcg levonorgestrel, one pill daily for first 21 days of each cycle through three cycles of 28 days. The last seven tablets in LD group contain placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Teaching Hospital

Full name of responsible person

Parvaneh Ghahremani nasab, Master of sciences student in midwifery

Street address

Baghshomal square, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr mohammadreza Rashidi

Street address

Golgasht Street, Tabriz

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Parvaneh Ghahremani nasab

Position

Master of sciences student in midwifery

Other areas of specialty/work

Street address

South Shariati street, Faculty of Nursing and Midwifery

City

Tabriz

Postal code

5173957675

Phone

+98 41 1478 8109

Fax

Email

ghahremani.parvaneh@yahoo.com

Web page address

http://nursing.tbzmed.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahnaz Shahnazi

Position

Master of Sciences of Midwifery

Other areas of specialty/work

Street address

South Shariati street, Faculty of Nursing and Midwifery

City

Tabriz

Postal code

51745347

Phone

+98 41 1477 2699

Fax

+98 41 1479 6969

Email

mshahnazi@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Parvaneh Ghahremani nasab

Position
Master of sciences student in midwifery

Other areas of specialty/work

Street address
South Shariati street, Faculty of Nursing and Midwifery

City
Tabriz

Postal code
51745347

Phone
+98 41 1478 8109

Fax

Email
ghahremani.parvaneh@yahoo.com

Web page address
http://nursing.tbzmed.ac.ir/

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