

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of herbal medicine (Mixture) on Polycystic ovary syndrome (PCOS) in women and girls with PCOS sign and symptom

Protocol summary

Summary

The aim of study is evaluation of the effects of herbal medicine (Mixture) on Polycystic ovary syndrome (PCOS) in females 60 patients aged 20-35 that are not willing to fertility or single women due to menstrual disorders or hirsutism and acne referred to Al-Zahra infertility health research center. In case of the diagnosis of polycystic ovary syndrome the consent form will taken and include to study. In case of drug intolerance or dissatisfaction in any stage of the study and body mass index above 30, they are free to withdraw any time. In this study, patients randomly will divided into 2 groups, 30 persons in each. Control group: will received an oral contraceptives for 3 menstrual cycles from the 5th day of menstruation for a period of 21 days. Intervention group: an oral contraceptives per day with continuous treatment of 700mgs herbal medicine per day for 3 months. Method of Preparation of Herbal Medicine 700mg: Cinnamon, Ginger, Orange peel and Mentha longifolia will purchased from natural habitats and reputable sources and then washed and dried then Pune 250 mg + ginger 200 mg + cinnamon 150 mg and 100 mg of orange peel will grounded and mixed together and each empty capsule will filled with this mixture and will administered to intervention population. The adjustments of dose will done by pharmacognosist. Before treatment, the consent form will taken from the subjects and for FSH, LH, estradiol, cholesterol, triglycerides, LDL, HDL, testosterone, FBS, insulin, sonography to evaluate the dimension, size and number of follicles in the ovaries and fill up the questionnaire that contain questions regarding clinical signs of PCO such as; status of menstrual cycle, hirsutism, acne and period of infertility. After 3 and 6 months of treatment, the study population will again subjected to a repeat sonography and tests. Eliminating or reducing the clinical symptoms of hirsutism and acne and regular menstrual cycle will be reviewed as a consequence of the initial plan. The study is not blinded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609015942N4**

Registration date: **2016-10-02, 1395/07/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-02, 1395/07/11

Registrant information

Name

Aliye Ghasemzadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3553 9160

Email address

gasemzadeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2016-09-27, 1395/07/06

Expected recruitment end date

2017-09-28, 1396/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of herbal medicine (Mixture) on Polycystic ovary syndrome (PCOS) in women and girls with PCOS sign and symptom

Public title

Evaluation of the effects of herbal medicine (Mixture) on Polycystic ovary syndrome (PCOS) in women and girls with PCOS sign and symptom

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: In case of the diagnosis of polycystic ovary syndrome the consent form will taken and include to study Exclusion criteria: In case of drug intolerance or dissatisfaction in any stage of the study and body mass index above 30; they are free to withdraw any time.

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

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

Ethics Committee Of Tabriz University Of Medical Sciences.

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Postal code

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.TBZMED.REC.1395.538

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Clinical symptoms of hirsutism

Timepoint

3 and 6 months after treatment

Method of measurement

Ultrasound and tests

2

Description

Clinical symptoms of acene

Timepoint

3 and 6 months after treatment

Method of measurement

Ultrasound and tests

Secondary outcomes

empty

Intervention groups

1

Description

Control group: will received an oral contraceptives for 3 menstrual cycles from the 5th day of menstruation for a period of 21 days.

Category

Treatment - Drugs

2

Description

Intervention group: an oral contraceptives per day with continuous treatment of 700mgs herbal medicine per day for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Aliye Ghasemzadeh

Street address

Alzahra Hospital, South Artesh St.,Tabriz, iran

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Alireza Rashidi

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

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,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

Aliye Ghasemzadeh

Position

Associate Professor of Obstetrics and Gynecology

Other areas of specialty/work**Street address**

Tabriz University Of Medical Sciences, Golgasht Street

City

Tabriz

Postal code**Phone**

+98 41 3553 9161

Fax**Email**

lahroudin@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University Of Medical Sciences

Full name of responsible person

Aliye Ghasemzadeh

Position

Associate Professor of Obstetrics and Gynecology

Other areas of specialty/work**Street address**

Tabriz University Of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3553 9161

Fax**Email**

lahroudin@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University Of Medical Sciences

Full name of responsible person

Aliye Ghasemzadeh

Position

Associate Professor of Obstetrics and Gynecology

Other areas of specialty/work**Street address**

Tabriz University Of Medical Sciences Tabriz , Golgasht Street, Tabriz

City

Tabriz

Postal code**Phone**

+98 41 3553 9161

Fax**Email**

lahroudin@gmail.com

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