Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 reseach 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 continouos 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 thenPune 250 mg + ginger 200 mg + cinnamon150 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 adjustions 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

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Aliye Ghasemzadeh
Name of organization / entity
Tabriz University of Medical Sciences
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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
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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