

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 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 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**

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

Tabriz University Of Medical Sciences

**Full name of responsible person**

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**Position**

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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*