

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Anti-Mullerian Hormone levels after laparoscopic treatment in women with anovulatory polycystic ovary syndrome

#### Protocol summary

##### Summary

1) Objectives: Because of unilateral laparoscopic ovarian is one of the main ways to induction of ovulation in patients with polycystic ovarian syndrome, this study investigated respond patients to the treatment method. 2) Design: For this study, patients with polycystic ovarian syndrome selected who didn't respond to clomiphene citrate drug treatment. 3) Setting and conduct: Patients randomly were divided into two groups, treated with clomiphene citrate and patients undergoing laparoscopic ovarian. This study was done at alzahra hospital, Tabriz-Iran on 60 patients. At first, serum samples were obtained to measurement anti-mullerian hormone assay then, 1 week, 1 and 3 months after the treatment protocol the measurement were performed. The patients response to treatment method was evaluated. 4) Participants including major eligibility criteria: Inclusion criteria include patients with polycystic ovary syndrome; PCOS patients resistance to drug clomiphene citrate; patients with symptoms of amenorrhea and exclusion criteria include patients with symptoms of oligomenorrhea; patients who were outside the age range. 5) Intervention: Intervention group include unilateral ovarian laparoscopic treatment in patients with polycystic ovary syndrome who resistant to drug treatment with a daily dose of 250 mg clomiphene citrate. Control group include clomiphene citrate administration with dose of 250 mg daily for 6 months in patients with polycystic ovary syndrome. 6) Main outcome measures: Serum anti-mullerian levels.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015020420374N2**

Registration date: **2015-03-23, 1394/01/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-03-23, 1394/01/03

##### Registrant information

###### Name

Esmat Aghadavod

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5554 0021

###### Email address

aghadavod@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Tabriz University of medical Sciences

##### Expected recruitment start date

2009-03-20, 1387/12/30

##### Expected recruitment end date

2009-10-22, 1388/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Anti-Mullerian Hormone levels after laparoscopic treatment in women with anovulatory polycystic ovary syndrome

##### Public title

Anti-Mullerian Hormone levels after laparoscopic treatment in women with anovulatory polycystic ovary

syndrome

## Purpose

Screening

## Inclusion/Exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome; PCOS patients resistance to drug clomiphene citrate; patients with symptoms of amenorrhea.

Exclusion criteria: Patients with symptoms of oligomenorrhea; patients who were outside the age range.

## Age

From **25 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)

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

Ethics Committees of Tabriz university of medical sciences

##### Street address

Medical faculty, Tabriz University of Medical Sciences  
, Daneshgah Blv, Tabriz, Iran

##### City

Tabriz

##### Postal code

#### Approval date

2009-06-06, 1388/03/16

#### Ethics committee reference number

5/4/2353

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovary syndrome

## ICD-10 code

E28.2

## ICD-10 code description

Sclerocystic ovary syndrome

## Primary outcomes

### 1

#### Description

Serum anti-mullerian levels

#### Timepoint

Pre-treatment and 1 week, 1 and 3 month after treatment

#### Method of measurement

Serum anti-mullerian hormon levels on nanomoles per mml

## Secondary outcomes

### 1

#### Description

Ovarian response to treatment method

#### Timepoint

1 and 3 month

#### Method of measurement

The first menstrual cycle after treatment

## Intervention groups

### 1

#### Description

Unilateral ovarian laparoscopic treatment in patients with polycystic ovary syndrome who resistant to drug treatment with a daily dose of 250 mg clomiphene citrate

#### Category

Treatment - Surgery

### 2

#### Description

The control group was clomiphene citrate administration with dose of 250 mg daily for 6 months in patients with polycystic ovary syndrome

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fertility center-Alzahr hospital

##### Full name of responsible person

Mis Oshaghi

##### Street address

Fertility center- Alzahra haspital, Daneshgah Blv,

Tabriz, Iran  
**City**  
Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vise chancellor for research, Tabriz University of Medical Sciences  
**Full name of responsible person**  
Mis Shasar  
**Street address**  
Medical faculty, Tabriz University of Medical Sciences, Danshgah Blv, Tabriz, Iran  
**City**  
Tabriz

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vise 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**  
Kashan university of Medical sciences  
**Full name of responsible person**  
Dr.Esmat Aghadavod Jolfaie  
**Position**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Women's Reproductive Health Research Center, Tabriz-Iran  
**Full name of responsible person**  
Dr.Layia Farzadi  
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Professor of Gynecology and Infertility  
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## Person responsible for updating data

### Contact

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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*

