

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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 oligomenorrhe; 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 Committes of Tabrz 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 menstural 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 haspital

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,
Dانشگاه 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

PhD

Other areas of specialty/work

Street address

Medical faculty, Kashan University of Medical
Sciences, Ravand road, Kashan, Iran

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

Aghadavod_m@yahoo.com

Web page address

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

Position

Professor of Gynecology and Infertility

Other areas of specialty/work

Street address

Medical faculty, Tabriz university of medical sciences,
Tabriz, Iran

City

Tabriz

Postal code

Phone

+98 41333364666

Fax

Email

Farzadil@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Esmat Aghadavod Jolfaie

Position

PhD

Other areas of specialty/work

Street address

Medical faculty, Kashan uinversity of Medical
Sciences, Ravand road, Kashan,Iran

City

Kashan

Postal code

Phone

+98 31 5554 0021

Fax

Email

Aghadavod_m@yahoo.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

