

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of the effects of laparoscopic ovarian drilling on ovarian reserve using unipolar cautery or CO2 laser in infertile patients with polycystic ovary syndrome

Protocol summary

Summary

In this single blinded study that was performed in a private fertility center under supervision of a university affiliated IVF ward, twenty infertile women with diagnosis of polycystic ovarian syndrome (PCOS) were randomized according to "Table of Random Numbers" in 2 groups. Each group contained 10 women. The patients with Positive history of previous pelvic surgery; evidence of pelvic adhesion /abnormality or Pregnancy were excluded. The selected patients were treated by laparoscopic unipolar ovarian cauterization (group 1) or CO2 laser drilling (group 2). Infertility was defined as failure to achieve pregnancy after one year unprotected sexual intercourse. The criteria for diagnosis of PCOS were: oligomenorrhea/ amenorrhea, sonographic findings in favor of polycystic ovaries (more than 10 primary follicles in each ovary), and clinical or biochemical evidence of hyperandrogenism. In group 1, fifteen cauterization points were applied by unipolar cautery on the middle line of both ovaries with the cautery degree in grade 5 (Karl Storz- Germany). In group 2, twenty-five laser points were applied by CO2 laser with power of 25 Watt (Ompilas 50, Zisse CO2 laser) on the same surface of ovaries like group1. Blood sampling for LH, FSH, total testosterone, AMH and inhibin B were obtained before operation (sample 1) and 3 months (sample 2), 6 months (sample 3) after operation. These biochemical tests were showed the ovarian reserve. The comparison was made between the result of these tests to show qualities of ovarian reserve before and after operation in each group. The primary outcomes were differences in serum levels of AMH and inhibin B before and after operations. The secondary outcome were serum levels of FSH, LH and total testosterone before and after operations. The laboratory staff were not aware of the kind of operation and timing of sampling.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091636164N1**
Registration date: **2017-11-05, 1396/08/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-05, 1396/08/14

Registrant information

Name

Nasrin Moghadami

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 982186089075

Email address

n_moghadami@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dr Dabirashrafi Fertility Center

Expected recruitment start date

2016-04-25, 1395/02/06

Expected recruitment end date

2016-12-31, 1395/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of laparoscopic ovarian drilling on ovarian reserve using unipolar cautery or CO2 laser in infertile patients with polycystic ovary syndrome

Public title

Comparison of cautery and laser in polycystic ovary syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were as follow: Having 2 criteria from 3 of Rotterdam criteria for diagnosis of PCOD; oligomenorrhea or amenorrhea; Clinical or biochemical evidence of hyperandrogenism; Sonographic findings of polycystic ovary (more than 10 primary follicle in each ovary) Exclusion criteria: Positive history of previous pelvic surgery; Evidence of pelvic adhesion; Evidence of pelvic organ abnormality; Pregnancy

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Tehran University of Medical Sciences

Street address

Building No.1, The Northern Gate of the University, Poursina Ave., Ghods Ave., Enghalab St.

City

Tehran

Postal code

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.TUMS.REC1395.2446

Health conditions studied

1

Description of health condition studied

Poly cystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Serum Anti Mullerian hormone levels

Timepoint

Three and 6 months after operation

Method of measurement

Serum AMH levels by Gen II ELIZA

2

Description

Serum Inhibin B levels

Timepoint

Three and 6 months after operation

Method of measurement

Serum Inhibin B levels by ELIZA Gen II

Secondary outcomes

1

Description

serum FSH level

Timepoint

Three and 6 months after operation

Method of measurement

Solid-phase sandwich enzyme- immunoassay

2

Description

Serum LH level

Timepoint

Three and 6 months after operation

Method of measurement

Solid-phase sandwich enzyme- immunoassay

3

Description

Serum total testosterone level

Timepoint

Three and 6 months after operation

Method of measurement

ELIZA

Intervention groups

1

Description

Intervention 1 Laparoscopic ovarian drilling by uni polar cautery will be performed in group 1 . In this method , 15 points of unipolar cautery (Karl Storz - Germany) will be applied with grade 5 cautery degree

Category

Treatment - Surgery

2

Description

Intervention 2 laparoscopic ovarian drilling by CO2 Laser (Ompilas ,Ziess) will be done for group 2 . In this method 25 points on the medial aspect of ovary will be cauterized.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Dabirashrafi Fertility Center

Full name of responsible person

Nasrin Moghadami

Street address

NO 54, Hoveyze Ave., Sohrevardi St., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dr Dabirashrafi Fertility Center

Full name of responsible person

Hormoz Dabirashrafi

Street address

No 54, Hoveyze Ave., Sohrevardi St., Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Dr Dabirashrafi Fertility Center

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

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Moghadami

Position

Faculty Member

Other areas of specialty/work

Street address

Yas Hospital, North Nejatollahi Ave., Karimkhan St.

City

Tehran

Postal code

1597856511

Phone

+98 21 8876 2345

Fax

Email

n_moghadami@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Moghadam

Position

Faculty Member

Other areas of specialty/work

Street address

Yas Hospital, North Nejatallah Ave., Karimkhan St.

City

Tehran

Postal code

1597856511

Phone

+98 21 8876 2345

Fax

Email

n_moghadami@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nasrin Moghadam

Position

Faculty member

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

Yas Hospital, North Nejatallah Ave., Karimkhan St.

City

Tehran

Postal code**Phone**

+98 21 8608 9075

Fax**Email**

maeb214@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

Data Dictionary

empty