Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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 polycyctic 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 testestrone 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
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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