

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Oct 2026

Comparison of ovulation rate in unilateral and bilateral ovarian electrocautery in infertile women with Clomiphene citrate resistant polycystic ovarian syndrome

Protocol summary

Summary

The aim of this study is to compare unilateral and bilateral ovarian drilling in terms of menstrual cycle, hormonal profile after surgery ovulation and pregnancy rate in patients with polycystic ovarian syndrome. The inclusion criteria: age: 20-38, BMI<32, infertile women with disorders of ovulation for more than 1 year, normal semen analysis in partner, normal HSG, resistance to Clomiphene citrate, absence of any major disease. The exclusion criteria: Other cause of infertility, use of other indicated ovulation diets, like Metformin, any abnormalities of fallopian tubes, endometriosis during laparoscopy. All unovulatory patients with Clomiphene citrate resistant polycystic ovarian syndrome that visit in infertility clinic between July 2010 to July 2011 will be studied if they candidate for ovarian drilling by infertility fellowship. Patients will be assessed by transvaginal sonography and hormonal profile (FSH, LH, testosterone in third day of menstrual cycle) before study. Hundred patients will randomly allocate to either unilateral or bilateral ovarian drilling. The ovulation rate, hormonal level and rate of pregnancy will be compared in two groups during 6-month follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903291306N2**
Registration date: **2010-10-03, 1389/07/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-03, 1389/07/11

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research - Guilan university of medical sciences

Expected recruitment start date

2010-07-23, 1389/05/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ovulation rate in unilateral and bilateral ovarian electrocautery in infertile women with Clomiphene citrate resistant polycystic ovarian syndrome

Public title

Comparison of ovulation rate after Laparoscopic electrocautery in infertile women with Clomiphene citrate resistant polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age: 20-38, BMI<32, infertile women with polycystic ovarian syndrome and infertility duration more than 1 year caused by disorder of ovulation, normal semen analysis in partner, normal hystrosalpangography, rsistance to Clomiphene citrate, absence of any major disease. Exclusion criteria: Other cause of infertility, use of other indicated ovulation diets like Metformin, any abnormalities of fallopian tubes and endometriosis during laparoscopy.

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Reasearch vice chancellorship_Guilan University of Medical Sciences

Street address

Namjo street

City

Rasht

Postal code

Approval date

2010-07-15, 1389/04/24

Ethics committee reference number

1694

Health conditions studied

1

Description of health condition studied

Female infertility associated with anovulation

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes

1

Description

ovulation rate

Timepoint

every month up to 6 months

Method of measurement

Observing ovulation signs in serial transvaginal sonography and measuring progesterone level at 21th day of menstrual cycle

Secondary outcomes

1

Description

serum hormonal level (FSH, LH, testosterone)

Timepoint

Third day of first menstrual cycle after laparoscopy

Method of measurement

According to FSH, LH (mIU/ml) and testosterone (nmol/ml)

2

Description

Clomiphene citrate dose for induction ovulation (If ovulation spontaneously don't return)

Timepoint

6 weeks and 10 weeks after laparoscopy

Method of measurement

Amount of Clomiphen citrate (mg) needed for ovulation

3

Description

pregnancy rate

Timepoint

during 6 month after laparoscopy

Method of measurement

Observing gestational sac in transvaginal sonography and positive serumal BhCG

Intervention groups

1

Description

Laparoscopic unilateral ovarian cauterization

Category

Treatment - Surgery

2

Description

Laparoscopic bilateral ovarian cauterization

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Reproduction health researcher center, Alzahra hospital

Full name of responsible person**Street address**

Namjo street

City

Rasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research vice chancellorship-Guilan university of Medical Science

Full name of responsible person

Dr.Abdolrasol Sobhani

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Namjo street

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Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research vice chancellorship-Guilan university of Medical Science

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

Guilan University of Medical Sciences

Full name of responsible person

Dr Ziba Zahiri

Position

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Postal code**Phone****Fax****Email****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*