Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the changes of Anti-Mullerian hormone and antral follicle number in polycystic ovarian syndrome resistant to clomiphene citrate, following ovarian drilling

Protocol summary

Study aim

Evaluation of the changes of Anti-Mullerian hormone and antral follicle number in polycystic ovarian syndrome resistant to clomiphene citrate, following ovarian drilling

Design

Laparoscopic ovarian drilling is performed on 30 patients. This is carried out at 4 to 6 points with a 4 mm monopolar needle electrode and 40 watts of electricity for 4 seconds at each point based on size of ovaries. Then, 3 and 6 months after surgery (or until pregnancy), the levels of Anti-Mullerian hormone, androgens, and antral follicles are checked.

Settings and conduct

All infertile women between 20 to 35 years old referring to Imam Reza and Milad Hospital of Mashhad, who have not been pregnant for one year and have had polycystic ovarian syndrome whose only cause of infertility is disorder in ovulation, Spouse's spermogram and radiography of hysterosalpingography are normal and after 6 days of treatment with no more than 150 mg per day of clomiphene for 5 days per each cycle have not had ovulation can enter the study.Blindness is not included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women with polycystic ovarian syndrome who have not been pregnant for one year and have been resistant to at least 6 courses of treatment with clomiphene. Age between 20 to 35 years. Normal spermogram of patient's spouse. Normal hysterosalpingography of patient. Exclusion criteria: Presence of problems in the spermogram. Report of tube obstruction in hysterosalpingography

Intervention groups

Intervention group: Infertile women aged 20 to 35 referring to Imam Reza and Milad Hospital, Mashhad, who have not been pregnant for one year and have had polycystic ovarian syndrome, and the only cause of their infertility is disorder in ovulation.

Main outcome variables

Effect of ovarian drilling on ovulation rate in women with polycystic ovarian syndrome resistant to clomiphene

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141230020486N4**
Registration date: **2018-08-18, 1397/05/27**
Registration timing: **retrospective**

Last update: **2018-08-18, 1397/05/27**
Update count: **0**

Registration date

2018-08-18, 1397/05/27

Registrant information

Name
Leili Hafizi
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-01-01, 1394/10/11

Expected recruitment end date

2018-08-02, 1397/05/11

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the changes of Anti-Mullerian hormone and antral follicle number in polycystic ovarian syndrome resistant to clomiphene citrate, following ovarian drilling

Public title
Evaluation of the changes of hormone in polycystic ovarian syndrome, following ovarian drilling
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women with polycystic ovarian syndrome who have not been pregnant despite having no protection for one year and have been resistant to at least 6 courses treatment with clomiphene Age between 20 to 35 years Normal spermogram of patient's spouse Normal patient hysterosalpingography Patient's consent to participate in the study
Exclusion criteria:
Presence of problems in the spermogram Report of tube obstruction in hysterosalpingography Patient's unwillingness to enter the study or at any stage of treatment Failure to follow up the patient
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
1358- 91735
Approval date
2015-07-22, 1394/04/31
Ethics committee reference number
IR.MUMS.fm.REC.1394.214

Health conditions studied

1

Description of health condition studied
polycystic ovarian syndrome
ICD-10 code
E28.2
ICD-10 code description
Polycystic ovarian syndrome

Primary outcomes

1

Description
Effect of ovarian drilling on hormones level in women with polycystic ovarian syndrome resistant to clomiphene
Timepoint
3 and 6 months after the ovarian drilling (or until pregnancy), the level of Anti-Mullerian hormone, androgens, antral follicles and ovulation rates are checked.
Method of measurement
The level of androgens (testosterone, DHEAS, androstenedione, and 17 hydroxyprogesterone), Anti-Mullerian hormone, the number of antral follicles by laboratory tests.

2

Description
Effect of ovarian drilling on ovulation rate in women with polycystic ovarian syndrome resistant to clomiphene
Timepoint
3 and 6 months after the ovarian drilling (or until pregnancy), ovulation rates are checked.
Method of measurement
Ovulation levels are monitored by serial vaginal sonography from the second day of the cycle to ovulation time.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Laparoscopic ovarian drilling is performed on patients with polycystic ovarian syndrome resistant to clomiphene. Then, 3 and 6 months after surgery (or until pregnancy), the levels of Anti-Mullerian hormone, androgens, and antral follicles are checked.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Leili Hafizi
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2

Recruitment center
Name of recruitment center
Milad Fertility Clinic
Full name of responsible person
Leili Hafizi
Street address
Milad Fertility research center, Beside Sina hospital, East Razi Street,
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Leili Hafizi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.
Under which criteria data/document could be used
Carrying out analysis on data is permitted.
From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.
What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.
Comments