

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

Email address

hafizil@mums.ac.ir

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

AgeFrom **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

Street address

Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

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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

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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 scientific inquiries

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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