

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Assessment of infertility treatment success by laparoscopic ovarian cautery in patients with poly cystic ovary syndrome and Previous failed IVF procedures referred to infertility clinic of Arash women hospital: a clinical trial

Protocol summary

Study aim

Assessment of infertility treatment success by laparoscopic ovarian cautery in patients with poly cystic ovary syndrome and Previous failed IVF procedures referred to infertility clinic of Arash women hospital: a clinical trial

Design

a randomized clinical trial with a parallel-group design of 34 patients. We will use the block randomization method by using: www.sealedenvelope.com

Settings and conduct

This clinical trial is conducted to evaluate 34 infertile eligible patients with PCOS who refer to Arash Women's Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with poly cystic ovary syndrome who have two of the three diagnostic criteria Rotterdam at least, age between 18- 35 year- old, body mass index less than 39, infertility for over a year, normal semen analysis in their spouse, previous failed IVF procedures at least for 2 times. Exclusion criteria: Aged more than 39 year- old

Intervention groups

In the intervention group, laparoscopic ovarian catheter surgery is performed for patients using 40-watt bipolar current at 4-6 points of the ovary and a month later, IVF / ET cycle treatment is performed. In the control group, patients enter the IVF / ET cycle without laparoscopic ovarian catheterization.

Main outcome variables

The oocyte and embryo quality, pregnancy loss, clinical pregnancy rate, pregnancy complications (gestational diabetes, preterm delivery, hypertension, and preeclampsia) OHSS

General information

Reason for update

The trial completion was 9 months after the actual recruitment end date, which was corrected in the system.

Acronym

IRCT registration information

IRCT registration number: **IRCT20090526001952N14**
Registration date: **2021-02-17, 1399/11/29**
Registration timing: **retrospective**

Last update: **2022-12-13, 1401/09/22**

Update count: **2**

Registration date

2021-02-17, 1399/11/29

Registrant information

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-12-04, 1395/09/14

Expected recruitment end date

2017-03-31, 1396/01/11

Actual recruitment start date

2015-08-22, 1394/05/31

Actual recruitment end date

2017-03-31, 1396/01/11

Trial completion date

2018-01-01, 1396/10/11

Scientific title

Assessment of infertility treatment success by laparoscopic ovarian cautery in patients with poly cystic ovary syndrome and Previous failed IVF procedures referred to infertility clinic of Arash women hospital: a clinical trial

Public title

Assessment of pregnancy rate by laparoscopic ovarian cautery in patients with poly cystic ovary syndrome and Previous failed IVF procedures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with poly cystic ovary syndrome who have two of the three diagnostic criteria Rotterdam at least Age between 18- 35 year- old Body mass index less than 30 Normal semen analysis in their spouse Previous failed IVF procedures at least for 2 times No laparoscopic contraindications

Exclusion criteria:

Aged more than 39 year Previous ovarian surgery Co-existing endocrine diseases including diabetes mellitus, estrogen-dependent tumors, thyroid disease, Cushing's syndrome, or congenital adrenal hyperplasia

Age

From **18 years** old to **39 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is on the basis of a block randomization list which is designed by an epidemiologist colleague using the Stata software (LLC StataCorp, USA) version 13 and a block size of 6. The random allocation process is concealed by providing 34 consecutive treatment cards that is placed in sealed envelopes. A random 10-digit code is written without sequence and frame on each envelope. This relevant code is patient's identification number, and just the project methodologist has known that this code is related to which treatment group. When the doctor announces that a patient is eligible, the methodologist has provided the doctor with an envelope design and the desired treatment is selected based on the type mentioned in the envelope. The outcome's evaluator also is considered

of a third party person who is unaware of the type of treatment performed. The data analysis is performed by a statistician who is unaware of all the study's processes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences , Deputy of Research

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Qods St, Keshavarz Blvd

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1417653761

Approval date

2015-08-09, 1394/05/18

Ethics committee reference number

IR.TUMS.REC.1394.542

Health conditions studied**1****Description of health condition studied**

infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

Primary outcomes**1****Description**

Chemical pregnancy rate

Timepoint

Beta-hCG test 14 days after embryo transfer

Method of measurement

Laboratory kits for Beta-hCG assay

2**Description**

Clinical pregnancy rate
Timepoint
6 to 7 weeks after embryo transfer
Method of measurement
Observing the gestational sac along with fetal heart activity in vaginal ultrasound

Secondary outcomes

1

Description
oocyte quality
Timepoint
Ovum pick-up day
Method of measurement
The number of Metaphase II oocytes obtained on the day of ovulation, which is reported by the embryologist

2

Description
Abortion rate
Timepoint
before 20th week of pregnancy
Method of measurement
sonography

3

Description
Embryo quality
Timepoint
before transfer
Method of measurement
It is determined by the embryologist based on the number of blastomeres and the percentage of fragmentation, multinucleation and symmetry on the third day after oocyte retrieval.

4

Description
Live birth rate
Timepoint
The delivery of a fetus who shows evidence of life after that is entirely outside of the mother
Method of measurement
Through hospital reports and telephone follow-up of patients

5

Description
The pregnancy complications
Timepoint
during 9 months of pregnancy
Method of measurement
Complications such as premature delivery or premature rupture of the amniotic sac before 37 weeks of pregnancy and diagnosis of blood pressure above 140/90 (hypertension) along with edema and excretion of protein in the urine (Preeclampsia) as well as diagnosis

of gestational diabetes (fasting plasma glucose equal to or greater than 92 mg/dL) with glucose 1 hour after consuming 75 grams of glucose equal to or more than 180 mg/dL) is recorded through checking the hospital report and telephone follow-up.

6

Description
Ovarian hyperstimulation syndrome rate
Timepoint
3 and 10 days after ovarian puncture
Method of measurement
Examination of symptoms, signs of ovarian hyperstimulation (mild to moderate pain in the abdomen, bloating or increased waist size, nausea and vomiting, diarrhea, tenderness in the ovaries) and vaginal ultrasound

Intervention groups

1

Description
Intervention group: Laparoscopic ovarian drilling is performed using 40-watt bipolar current at 4-6 points of the ovaries for patients and a month later undergo in vitro fertilization (IVF) cycle with ovarian stimulation using an antagonist protocol.
Category
Treatment - Surgery

2

Description
Control group: In this group, patients without laparoscopic ovarian drilling are treated only for in-vitro fertilization (IVF) cycle with ovarian stimulation using antagonist protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Ashraf Moieni
Street address
Arash women's hospital, Reslat highway, Tehranpars, Rashid Ave.
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A_moini@royaninstitute.org

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

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Sakineh Normohamadi

Position

Resident

Latest degree

Medical doctor

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

Arash women's hospital, Reslat highway, Tehranpars, Rashid Ave.

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Full name of responsible person

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Position

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Latest degree

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available