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

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Name of organization / entity
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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
Street address
Qods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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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