Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of adding L-carnitine during ovarian stimulation with antagonistic protocol in patients with polycystic ovarian syndrome (PCOS) on the outcome of in-vitro fertilization/intracytoplasmic sperm injection (IVF / ICSI) cycle: A double-blind randomized clinical trial

Protocol summary

Study aim

To evaluate the effect of oral L-carnitine supplementation during controlled ovarian stimulation (COS) in patients with polycystic ovary syndrome (PCOS) in a double-blind randomized clinical trial

Design

A controlled randomized double-blind clinical trial with parallel groups, phase III

Settings and conduct

The study at Royan Research Institute was designed as a clinical trial and both patients and researchers will not be aware of the type of grouping and only the main researcher who is not involved in the sampling process will know the coding of the main drugs and placebo.

Participants/Inclusion and exclusion criteria

All patients with a diagnosis of polycystic ovary syndrome will be evaluated according to Rotterdam criteria who were eligible and had written consent to participate in the study.

Intervention groups

The controlled ovarian stimulation procedure in all the study participants will be the same by using a flexible regimen of GnRH-antagonist with E2 priming. In the experimental group, the women received 3 tablets of L-carnitine daily (L-carnitine® tablet 1000 mg, Karen Pharmaceutical Company, Iran) from day 2 of the previous menstrual cycle until pregnancy test day. The method of ovarian stimulation in the control group is completely similar to the intervention group and they take placebo tablets instead of L-carnitine supplements.

Main outcome variables

Total number of retrieved oocytes; Total number of MII oocytes;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080831001141N42**
Registration date: **2023-07-19, 1402/04/28**
Registration timing: **retrospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **0**

Registration date

2023-07-19, 1402/04/28

Registrant information

Name

Kiandokht Kiani

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 7960

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-01, 1398/12/11

Expected recruitment end date

2022-12-29, 1401/10/08

Actual recruitment start date

2023-02-28, 1401/12/09

Actual recruitment end date

2023-02-28, 1401/12/09

Trial completion date
2023-02-28, 1401/12/09

Scientific title
The effect of adding L-carnitine during ovarian stimulation with antagonistic protocol in patients with polycystic ovarian syndrome (PCOS) on the outcome of in-vitro fertilization/intracytoplasmic sperm injection (IVF / ICSI) cycle: A double-blind randomized clinical trial

Public title
The effect of L-carnitine supplementation on the results of infertility treatment cycle in women with polycystic ovary syndrome

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients between 20 to 37 years old, presenting with primary or secondary infertility following regular intercourse for at least 1 year and diagnosed with PCO according to Rotterdam's criteria who had received two to three failures of intrauterine insemination (IUI) cycle therapy were included. The diagnosis was based on a complete history taking, physical examination, and a complete file documented infertility work-up within the previous 6 months, either conducted within the setting of the hospital or at a licensed infertility management clinic.

Exclusion criteria:
Patients diagnosed with hyperprolactinemia, diabetes mellitus, epilepsy, and/or any chronic endocrine and cardiovascular diseases Patients are treated with a special diet, medication supplement (ovaboost), and metformin before or during ovarian stimulation History of pelvic surgery on ovaries and uterus Presence of submucosal and intramural fibroids larger than 5 cm or the presence of uterine polyps and congenital uterine malformations The cause of severe male infertility (sperm extraction through surgery)

Age
To **37 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**
Actual sample size reached: **97**

Randomization (investigator's opinion)
Randomized

Randomization description
The medicine packages, as well as the appearance and smell of L-carnitine and placebo tablets, are completely similar to each other. The methodologist prepared the drugs based on the block randomization method and prepared the coded list and put an English three-letter code label on the medicine cans. When an eligible patient is referred to a clinical physician, the principal investigator provides him with an envelope containing a drug code based on a randomized list, and the drug package with the same code is delivered to the patient. In this way, the patient and the clinical doctor following the patient will not know the type of drug (L-carnitine or placebo).

Blinding (investigator's opinion)
Double blinded

Blinding description
The patients in the control group will receive 3 placebo tablets for 8 weeks. All the placebo tablets were produced by Karen company (Tehran, Iran), which is approved by the Food and Drug Administration of Iran. The appearance of the placebo was indistinguishable in color, shape, size, and smell from L-carnitine tablets.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
Clinical trials.gov

Secondary trial Id
NCT04672720

Registration date
2020-12-17, 1399/09/27

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Royan Research Institute

Street address
No. 12, Hafez Sharghi St., North Bani Hashem St., Shahid Soleimani Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1165659711

Approval date
2018-10-10, 1397/07/18

Ethics committee reference number
IR.ACECR.ROYAN.REC.1397.156

Health conditions studied

1

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

Primary outcomes

1

Description
Total number of retrieved oocytes
Timepoint
Day of oocyte pick-up, 32-34 hours after hCG administration (approximately Stimulation Day 10)
Method of measurement
At the point of ovum pick-up, we can count the total number of retrieved oocytes. Therefore, in one hour after ovum pick-up, outcome measurement will be possible.

2

Description
Total number of mature (MII) oocytes
Timepoint
Day of oocyte pick-up, 32-34 hours after hCG administration (approximately Stimulation Day 10)
Method of measurement
At the point of ovum pick-up, we can count the total number of mature (MII) oocytes. Therefore, in one hour after ovum pick-up, outcome measurement will be possible.

Secondary outcomes

1

Description
Fertilization rate
Timepoint
17-18 h after intracytoplasmic sperm injection and/or in-vitro insemination by checking the number of polar bodies and pronuclei
Method of measurement
The fertilization rate was defined as the ratio between the number of diploid zygotes and the number of mature oocytes

2

Description
Quality of obtained embryos
Timepoint
3 days after IVF/ICSI procedure
Method of measurement
Embryo grade was assessed under an inverted microscope 3 days after the intracytoplasmic sperm injection procedure. The quality of embryos was graded from 1 to 3 under inverted microscope 3 days after the intracytoplasmic sperm injection procedure. Embryos with even-sized blastomeres and/or ≤10% fragments were classified as Grade 1 (Excellent or good quality). Grade 2 embryos (moderate or fair quality) had blastomeres with slightly-moderate size differences and/or 10- 20% fragments. Grade 3 embryos (poor quality) had markedly different-sized blastomeres and/or >20% fragments.

3

Description
Clinical pregnancy rate
Timepoint
7 weeks after embryo transfer
Method of measurement
It was defined as the presence of a gestational sac with a heartbeat under vaginal ultrasonography

Intervention groups

1

Description
In the experimental group: patients receive 3 grams daily (3 tablets of L-carnitine 1000 mg, Karen Pharmaceutical Company, Iran) from the second day of menstruation of the previous cycle until the day of the pregnancy test (for 8 weeks).
Category
Treatment - Drugs

2

Description
In the control group: patients receive 3 placebo tablets daily (containing cellulose similar to L-carnitine tablets in terms of size, shape, color, and smell, Karen Pharmaceutical Company, Iran) from the second day of menstruation of the previous cycle until the day of the pregnancy test (for 8 weeks).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Royan Institute
Full name of responsible person
Maryam Hafezi
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No. 12, Shahid Soleimani Highway, Bani Hashem St., East Hafez St., Royan Institute
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Dr. Parvaneh Afsharian

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pafshar@royaninstitute.org

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Royan Institute

Proportion provided by this source

100

Public or private sector

Private

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

Royan Institute

Full name of responsible person

Arezoo Arabipoor

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Maryam Hafezi

Position

Assistance 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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Full name of responsible person

Arezoo Arabipoor

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Reseacher

Latest degree

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Other areas of specialty/work

Midwifery

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The personal data of the participants in the study as well as the data related to the main outcome will be reported between the two groups without mentioning their names.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The study data will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers who intend to write a review and meta-analysis study can access the project data and documentation through correspondence with the project facilitator, whose details are provided on the site.
From where data/document is obtainable
To access the documents and raw data, it is necessary to study the administrative correspondence with the research deputy of Royan Institute and correspondence with the respondent whose details have been announced on the site.
What processes are involved for a request to access data/document
6 months after the publication of the article in scientific journals, they can send their request through official correspondence or email with the research deputy of the Royan Institute. Access to the data may take up to one month after the application is submitted.
Comments