Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation the effect of adding L-carnitine to clomiphene resistant PCOS women on the ovulation and the pregnancy rate

Protocol summary

Study aim
Evaluation of the effect of adding L-carnitine to ovulation stimulation treatment of clomiphene-resistant PCOD women on ovulation and pregnancy

Design
Clinical trial with control group, with parallel groups, triple-blind, randomized, phase 2 on 148 patients. To randomize, Balanced Block Randomization method was used.

Settings and conduct
The effect of L-carnitine addition to ovulation stimulation treatment of clomiphene-resistant PCOD women on ovulation and pregnancy. Location of infertility clinic of Imam Hossein Hospital in Tehran. The researcher, patient, nurse, and data analyzer were blinded to the type of group the patient was in. 148 patients of Iranian infertile women with clomiphene-resistant PCOD were divided into control and intervention groups by random allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosed as PCOS; hysterosalpingography (HSG) normal; semen analysis normal spouse. Exclusion criteria: the patient's unwillingness to continue the study; other pathology of the uterus and ovaries; tube infertility diagnosed with hysterosalpingogram (HSG).

Intervention groups
Patients who have received clomiphene for three months and have not become pregnant will be randomly divided into two groups. The first group will be re-induced with clomiphene three months later and the second group will be treated with L-carnitine (capsule) in addition to clomiphene.

Main outcome variables
Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210415050980N1**
Registration date: **2021-05-02, 1400/02/12**
Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**
Update count: **0**

Registration date
2021-05-02, 1400/02/12

Registrant information

Name
Minoo Hashemzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2243 9770

Email address
minoohashemzadeh9@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-09-22, 1400/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of adding L-carnitine to clomiphene resistant PCOS women on the ovulation and the pregnancy rate

Public title
Evaluation of the effect of adding L-carnitine to the treatment of ovulation stimulation in women with polycystic ovaries
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
PCOS Normal Hysterosalpingo-graphy (HSG) Normal Semen analysis
Exclusion criteria:
The patient's unwillingness to continue the study Other pathology of the uterus and ovaries Tubal infertility diagnosed with Hysterosalpingogram (HSG)
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked

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

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random: in this method, first the list of names of all patients will be obtained, then a number will be assigned to each of them and the required number will be selected using a table of random numbers.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, the patient will not be aware of the type of study group in which she is placed, nor will the researcher, patient care nurse, and data analyzer be aware of the type of patient grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
7th Floor, Bldg No.2, SBUMS, Arabi Ave., Velenjak
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2019-06-18, 1398/03/28
Ethics committee reference number
IR.SBMU.MSP.REC.1398.272

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
Clinical pregnancy
Timepoint
At the beginning of the study and after the end of the study
Method of measurement
Sonography

Secondary outcomes

empty

Intervention groups

1

Description
Control group: patients who received clomiphene for three months and were not pregnant and will be re-induced with clomiphene three months later.
Category
Placebo

2

Description
Intervention group: patients who have been receiving clomiphene for three months and have not become pregnant will be treated with L-carnitine (capsule) in addition to clomiphene.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person
Minoo Hashem-Zadeh

Street address
Tehran Province, Tehran, Velenjak، 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Robabeh Taheri-Panah

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave., Velenjak

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Email
Mpajouhesh@sbmu.ac.ir

Web page address
http://research.sbmu.ac.ir/index.jsp?fkeyid=&siteid=24&pageid=148

Grant name
Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences

Proportion provided by this source
10

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Minoo Hashemzadeh

Position
Resident

Latest degree
Medical doctor

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Total data

When the data will become available and for how long
Access period starts from 1401

To whom data/document is available
Researcher

Under which criteria data/document could be used
Research

From where data/document is obtainable
Minoo Hashemzadhe

What processes are involved for a request to access data/document
Email

Comments