

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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
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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

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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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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

Mino Hashemzadhe

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

Email

Comments