Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of administering L-Carnitine to Clomiphene citrate stimulated cycles on ovulation and conception rate in infertile women with polycystic ovary syndrome: a randomized controlled clinical trial in Kabul.

Protocol summary

Study aim

Determination of the effect of L-Carnitine in ovulation stimulation cycles with clomiphene citrate on pregnancy and ovulation rates of infertile women with polycystic ovary syndrome in Kabul

Design

Clinical trial with control group, with parallel group, three-blind, randomized 4-block, phase 3 on 32 samples

Settings and conduct

Sarcheshmeh complex of doctors and specialists and Kadri Khatam Al-Nabieen Hospital, Kabul

Participants/Inclusion and exclusion criteria

Women aged 20-35 years who visited for treatment of primary infertility due to polycystic ovary syndrome diagnosed according to Rotterdam criteria by a gynaecologist and having regular vaginal intercourse in the last year. The exclusion criteria are as follows: Infertility with other causes (such as male causes, tubular causes, etc.), allergy to L-Carnitine, pregnancy or lactation, Antimullerian hormone less than the normal range for age, having chronic diseases, the body mass index (BMI) over 30, using other antioxidants or supplements, using insulin releasing drugs, lipid-lowering agents, antiepileptic drugs, drugs with effects on endocrine system and carbohydrate metabolism from 3 months before the start of the study.

Intervention groups

In the intervention group, L-Carnitine capsules 1000 mg from the American company called Pride Puritan's (2 capsules, 1 gr) daily with clomiphene citrate tablets,100 mg from day 3 to 9 of Menstrual cycle will be used and in the control group clomiphene will be prescribed similar to the intervention group along with an L-carnitine-like placebo capsule containing milk powder and produced by the same company in Afghanistan.

Main outcome variables

Determining luteinizing hormone (LH) levels; Determining antimullerian hormone (AMH) levels; Determining the number of antral follicles; Determining chemical pregnancy and clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211204053267N1**
Registration date: **2021-12-30, 1400/10/09**
Registration timing: **prospective**

Last update: **2021-12-30, 1400/10/09**
Update count: **0**

Registration date

2021-12-30, 1400/10/09

Registrant information

Name

Aqila Chamanshahi

Name of organization / entity

Tarbiat Modares university

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3811

Email address

aqila.chamanshahi@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of administering L-Carnitine to Clomiphene citrate stimulated cycles on ovulation and conception rate in infertile women with polycystic ovary syndrome: a randomized controlled clinical trial in Kabul.

Public title

The effect of administering L-Carnitine to Clomiphene citrate stimulated cycles on conception rate and ovulation in infertile women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20-35 years old women Primary infertility due to polycystic ovary syndrome diagnosed according to Rotterdam criteria by a gynaecologist Having regular vaginal intercourse in the last year

Exclusion criteria:

Infertility with other causes (such as male causes, tubular causes, etc.) Allergy to L-Carnitine Pregnancy or lactation Antimullerian hormone less than the normal range for age Having chronic diseases The body mass index (BMI) over30 Using other antioxidants or supplements Using insulin releasing drugs, lipid-lowering agents, antiepileptic drugs, drugs with effects on endocrine system and carbohydrate metabolism from 3 months before the start of the study

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

In the first stage, the research units will be divided into two groups of intervention and control based on the inclusion and exclusion criteria of screening and then block randomization using quadruple random blocks. This method strikes a balance in the allocated samples. In this way, we first design blocks of 4 types of available probabilities, so that in each block there are two people from the intervention group and two people from the control group. The number of probabilities in this case will be equal to 6.AABB(1)-BBAA(2)-ABBA(3)- BAAB(4)-BABA(5)- ABAB(6). Then the list of available modes is prepared and numbered by the tutor, and the statics specialist sort the blocks based on random numbers from 1 to 6. Matte envelopes in the package will be used in numbered order to hide the allocation. The researcher randomly picks up the envelopes and then enters the research units into the sampling system in order.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be a phase 1 three-blind clinical trial with placebo control group. The method of blinding is that the researcher and the research units and statistical analysts will also be unaware of the type of drug used, and the placebo drug will be prepared by the pharmacist in the same form and with a special code and will be provided to the research units. Participants and researchers will be unaware of the drug codes and only the pharmacist will determine the drug code and after collecting and completing the study, these codes will be decoded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University Biomedical Research Ethics Committee

Street address

Pol Nasr

City

Jalal Al ahmad

Province

Tehran

Postal code

1411716911

Approval date

2021-12-25, 1400/10/04

Ethics committee reference number

IR.MODARES.REC.1400.259

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
The primary outcome of the study will be chemical pregnancy rate which means that β -HCG is more than 5 ml / ml, which is detected on the first day of the last menstrual cycle (LMP) at week 4-5 without the fetal heart and Or the pregnancy sac will be visible on ultrasound at 6-7 weeks.
Timepoint
3 times with intervals of 1 month
Method of measurement
Using a laboratory assay, β -HCG more than mIU/mL based on the first day of the last menstrual cycle (LMP) at week 4-5

2

Description
The LH hormone will be checked on the eighteenth to the twenty-second day of cycle after drug administration, which is normal in the luteal phase (0.61 to 16.3 IU/L). If the level of this hormone is reported outside the range compared to the first test of this ovulation stimulation hormone from the laboratory, it will be considered as the lack of effect of this drug on the ovulation cycle.
Timepoint
The LH levels will be checked on the eighteenth to the twenty-second day after the drug is administered
Method of measurement
The normal level of LH in the luteal phase is (0.61 to 16.3 IU/L)

3

Description
Number of antral follicles in infertile women with polycystic ovary syndrome, on the twelfth day of the menstrual cycle to the 22nd day of the menstrual cycle after the intervention
Timepoint
For 3 months, after the twelfth day of the menstrual cycle, every two days, serially until the 22nd day of the menstrual cycle to evaluate the effect of the drug on the ovary and polycystic ovary syndrome will be performed using transvaginal ultrasound.
Method of measurement
Using transvaginal ultrasound

4

Description
Clinical pregnancy in infertile women with polycystic ovary syndrome, after intervention
Timepoint
Monthly, 6-7 weeks from the first day of the last menstrual period for 3 months
Method of measurement
Finding the pregnancy sac and fetal heart using ultrasound at 6-7 weeks from the first day of the last menstrual period.

5

Description
Antimullerian hormone levels in infertile women with polycystic ovary syndrome, on the third day of the cycle
Timepoint
Monthly in the third day of menstruation will evaluate the antimullerian hormone (AMH) levels after the drug is administered
Method of measurement
This hormone is measured in infertile women with polycystic ovary syndrome on the third day of menstruation until the next cycle of bleeding, which is considered according to the patient's age according to the laboratory cut-off kit.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 16 people will be randomly selected, considering the sample size. L-Carnitine capsule 1000 mg from the American company called Pride Puritan's (2 capsules of 1 gram) daily with first-line infertility treatment drug (Clomiphene citrate tablets with a dose of 100 mg from day 3 to 9 of the menstrual cycle) will be used orally in the intervention group
Category
Treatment - Drugs

2

Description
Control group: In the control group, placebo capsule similar to L-carnitine, which will contain powdered milk and will be produced by the same company (Puritan's Pride) (2 capsules) daily with first-line infertility treatment drug (clomiphene tablets100 mg) from day 3 to 9 of the menstrual cycle will be used orally
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kedri Khatam AL Nabieen Hospital
Full name of responsible person
Shadab Shahali
Street address
Darulaman street
City
Kabul
Postal code
1001
Phone

+93 78 523 2020

Email

khatam.al.nabieen.hospital@gmail.com

2

Recruitment center

Name of recruitment center

Sarcheshmah Complex of doctors and specialists

Full name of responsible person

Shadab Shaali

Street address

Fiez Mohamd Kateb street

City

Kabul

Postal code

1001

Phone

+93 79 049 4763

Email

amanibrahimi78@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modars University

Full name of responsible person

Amir Abdullah zada

Street address

Jalal al Ahmad

City

Tehran

Province

Tehran

Postal code

1411716911

Phone

+98 21 8288 3522

Email

zadeh@modares.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tarbiat Modars University

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

Tarbiat Modares University

Full name of responsible person

Shadab Shahali

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Jalal al Ahmad

City

Tehran

Province

Tehran

Postal code

1411716911

Phone

+98 21 8288 3811

Email

shadab.shahali@modares.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shadab Shahali

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Jalal al Ahmad

City

Tehran

Province

Tehran

Postal code

1411716911

Phone

+98 21 8288 3811

Email

shadab.shahali@modares.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

Shadab Shahali

Position

Assistant Professor

Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
بزرگراه جلال آل احمد، دانشکده علوم پزشکی، دانشگاه تربیت مدرس
City
تهران
Province
Tehran
Postal code
1411716911
Phone
+98 21 8288 3811
Email
shadab.shahali@modares.ac.ir

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
To keep the security of data
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Only part of the data, including information about the main outcome, can be shared.
When the data will become available and for how long
Starting access period from 2023
To whom data/document is available
The data will only be available to field researchers
Under which criteria data/document could be used
For further research, researchers can send a written request to the responsible author
From where data/document is obtainable
Corresponding Author, Tarbiat Modares University, Faculty of Medical Sciences, Department of Reproductive Health and Midwifery
What processes are involved for a request to access data/document
After a written request from the responsible author, the request will be sent to the research unit of Tarbiat Modares University, and if the rules are complied with, the analyzed data will be provided to the researchers.
Comments