

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of alpha lipoic acid administration on the outcomes of assisted reproductive therapy in patients with polycystic ovarian syndrome

Protocol summary

Study aim

Determining the effect of alpha lipoic acid on oocyte number obtained during ovulation stimulation

Design

Clinical trial with control group with parallel groups, triple-blind, randomized, phase 3 on 40 patients. For randomization, the rand function of the Excel program is used to generate a random number between 1 and 2.

Settings and conduct

Patients referring to the infertility center of Hormozgan University of Medical Sciences after confirming the diagnosis of PCO based on the Rotterdam criteria, who are candidate for in vitro fertilization, taking into the exclusion and inclusion criteria completing the informed consent form. The participants, research assistants and researchers will not know how the groups will be assigned.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with PCO according to Rotterdam criteria between 18 and 37 years old; candidate for in vitro fertilization. Exclusion criteria: BMI greater than > 30; receiving OCPs in the last 3 months; systemic diseases; such as hyperlipidemia and cardiovascular metabolic syndrome; severe male factor, especially non-obstructive azoospermia; receive insulin.

Intervention groups

Intervention: receiving 600 mg/day of alpha lipoic acid for 2 months until the day of ovulation Control: receiving placebo daily for 2 months

Main outcome variables

The total number of obtained oocytes; the number of MII oocytes; quality of obtained oocytes; the number of fertilized oocytes; the number of embryos that have reached the cleavage stage; the number of embryos with good quality in each cycle; chemical pregnancy rate; clinical pregnancy rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048630N4**

Registration date: **2023-05-24, 1402/03/03**

Registration timing: **prospective**

Last update: **2023-05-24, 1402/03/03**

Update count: **0**

Registration date

2023-05-24, 1402/03/03

Registrant information

Name

Ensieh Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 76 3333 0755

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of alpha lipoic acid administration on the outcomes of assisted reproductive therapy in patients with polycystic ovarian syndrome

Public title

The effect of alpha lipoic acid administration on the outcomes of assisted reproductive therapy in patients with polycystic ovarian syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with polycystic ovary syndrome according to the Rotterdam criteria Women of reproductive age between 18 and 37 years Candidate for in vitro fertilization No endometriosis Absence of hydrosalpinx

Exclusion criteria:

BMI \geq 30 Secondary causes of obesity (hypothyroidism, Cushing's syndrome) High grade endometriosis III and IV Thyroid diseases Salpingitis and hydrosalpinx Congenital adrenal hyperplasia Hyperprolactinemia Ovarian secretory tumors Receipt of OCPs (steroids or other drugs that affect ovarian function, insulin sensitivity, and lipid metabolism) in the past 3 months, except for standardized PCOS treatment Lupus and autoimmune diseases Systemic diseases such as hyperlipidemia and cardiovascular metabolic syndrome Severe male factor, especially non-obstructive azoospermia (sperm count less than 5 million/ml) Receive insulin

Age

From **18 years** old to **37 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients (including 40 patients) are randomly assigned by a statistical expert using simple randomization method. In this method, the Random between function of the Excel program is used to generate a random number between the number 1 and 2. This work was repeated 40 times and thus a random sequence is obtained.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The participants, researcher and data analyzer will not know how the groups will be assigned.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Hormozgan University of medical sciences

Street address

Deputy of research and technology, campus of Hormozgan University of Medical Sciences, Imam Hossein boulevard, Bandar Abas, Iran

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Approval date

2022-12-12, 1401/09/21

Ethics committee reference number

IR.HUMS.REC.1401.307

Health conditions studied

1

Description of health condition studied

Poly cystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

polycystic ovarian syndrome

Primary outcomes

1

Description

The number of oocyte obtained

Timepoint

Two months after the start of the intervention

Method of measurement

Count the number

2

Description

The number of MII oocyte obtained

Timepoint

Two months after the start of the intervention

Method of measurement

Count the number

3

Description

Fertilization rate

Timepoint

Two months after the start of the intervention

Method of measurement

Count the number of formed zygote

Secondary outcomes**1****Description**

Biochemical pregnancy

Timepoint

14 days after embryo transfer

Method of measurement

Measurement of beta hormone serum level

2**Description**

Clinical pregnancy

Timepoint

6 weeks after embryo transfer

Method of measurement

Sonography

Intervention groups**1****Description**

Intervention group: receiving oral alpha lipoic acid capsule 600 mg daily for 2 months

Category

Treatment - Other

2**Description**

Control group: Receiving a placebo(containing flour) daily for two months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility Center of Hormozgan University of Medical Sciences

Full name of responsible person

Dr Maryam Azizi Kutenaee

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Shahid Mohammadi Hospital, Parastar Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr Vali Alipour

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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

Bandare-abbas 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**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr Maryam Azizi Kutenaee

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

The data will be presented in the article after analysis

When the data will become available and for how long

2025

To whom data/document is available

Academic researchers and gynecologists and obstetricians

Under which criteria data/document could be used

Application at the bedside in patients undergoing ICSI

From where data/document is obtainable

corresponding author of the article

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

Email to the corresponding author

Comments