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 alphalipoic 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
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Ensieh Salehi
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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≥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
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Full name of responsible person
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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
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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