

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluation of the effect of supplementation with vitamin E and vitamin D on serum and follicular fluid oxidative and anti oxidative stress factors, oocyte quality and ICSI outcomes in PCOS infertile women candidate for ICSI who referred to Infertility Clinic of Avicenna Research Center during 2014-2015

Protocol summary

Summary

The aim of this study is to assess the effects of vit E, vit D on serum and follicular fluid MDA, TAC, SOD and oocyte quality and ICSI out comes in infertile pcos women. For this purpose we enroll 100 infertile pcos women who need ICSI in avicenna infertility clinic during 2014-2015.they divide randomly in two groups.group1 receive 400IU vit E per day and 50000 IU vit D biweekly for 2 months and group 2 receive placebo for 2 months.both groups receive nutrition consult and they receive controlled low glycemic diet with balanced antioxidants and reduced trans fat.ICSI protocol is long in all patients. MDA, TAC, SOD are measured in serum twice: at the beginning of the study, before intervention and at the oocyte collection day and in follicular fluid on the oocyte collection day.antioxidant therapy seem to improve oocyte quality and ICSI outcomes due to reduce oxidative stress markers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081018662N1**

Registration date: **2014-08-21, 1393/05/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-21, 1393/05/30

Registrant information

Name

Farnaz Fatemi

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

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+98 21 2243 2020

Email address

f.fatemi@avicenna.ac.ir

Recruitment status

Recruitment complete

Funding source

Avicenna Infertility Clinic

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of supplementation with vitamin E and vitamin D on serum and follicular fluid oxidative and anti oxidative stress factors, oocyte quality and ICSI outcomes in PCOS infertile women candidate for ICSI who referred to Infertility Clinic of Avicenna Research Center during 2014-2015

Public title

Effect of vitamin E, vitamin D on treatment of infertility in PCOS patients

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria: PCOS patients based on ROTTERDOM criteria; age:18-38 years old; day3 FSH level less than 12; BMI:20-34. Exclusion criteria: patients with heart, liver or renal disease; patients with Endometriosis; use of anticoagulants: ASA, Heparin, Warfarin; use of antidepressants: Fluoxetine, Citalopram; use of Statins: Lovastatin, Atorvastatin; patients with Eye disease: Retinitis pigmentosa; use of anti-inflammatory drugs and corticosteroids: prednisolone; use of vitamins and antioxidants in 3 months ago; vit K deficiency and bleeding disorders; history of chemotherapy or radiotherapy

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Research Institute Ethics Committee

Street address

Avicenna Research Institute, Shahid Beheshti University, Velenjak Avenue, Chamran highway

City

Tehran

Postal code

1936773493

Approval date

2014-06-24, 1393/04/03

Ethics committee reference number

93/1709

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Sclerocystic ovary syndrome Stein-Leventhal syndrome

2

Description of health condition studied

Infertility

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes

1

Description

serum malonaldehyde

Timepoint

before intervention and after intervention on the oocyte collection day

Method of measurement

American key man kit

2

Description

serum total antioxidant capacity (TAC)

Timepoint

before intervention and after intervention on the oocyte collection day

Method of measurement

American key man kit

3

Description

serum super oxid dismutase

Timepoint

before intervention and after intervention on the oocyte collection day

Method of measurement

American key man kit

4

Description

follicular fluid malonaldehyde

Timepoint

on the oocyte collection day

Method of measurement

American key man kit

5

Description

follicular fluid total antioxidant capacity

Timepoint

on the oocyte collection day

Method of measurement

American key man kit

6**Description**

follicular fluid super oxid dismutase

Timepoint

on the oocyte collection day

Method of measurement

American key man kit

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

oocyte quality

Timepoint

on the day of oocyte collection

Method of measurement

morphologic assesment with microscope

2**Description**

ICSI outcome

Timepoint

2 weeks after embryo transfer

Method of measurement

serum BHCG

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

placebo of vit E once daily for 2 months

Category

Treatment - Drugs

2**Description**

pearl vit D,Biweekly for 2 months

Category

Treatment - Drugs

3**Description**

placebo of vit D,biweekly for 2 months

Category

Treatment - Drugs

4**Description**

pearl vit E,400 IU,once daily for 2 months

Category

Treatment - Drugs

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

Avicenna Infertility Clinic

Full name of responsible person

Dr. Farnaz Fatemi

Street address

No. 97, Yakhchal st., Shariati avenu,Tehran, Iran

City

Tehran

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

Avicenna Infertility Clinic

Full name of responsible person

Dr. Mohammad Mehdi Akhondi

Street address

No. 97, Yakhchal st., Shariati avenu,Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number**

93/1717

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

Yes

Title of funding source

Avicenna Infertility Clinic

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Avicenna Infertility Clinic

Full name of responsible person

Dr. Farnaz Fatemi

Position

MD,OB & GYN, Infertility fellowship

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Farnaz Fatemi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty