Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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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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 scienece
Inclusion/Exclusion criteria
Inclusion criteria: PCOS patients based on ROTERDOM 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 anticoagulats: ASA, Heparin, Warfarin; use of antidepresants:Fluoxetin, Certeralin; use of Statins: Levastatin, Atorvastatin; patients with Eye disease: Retinitis pigmentosa; use of anti inflammatory drugs and corticosteroids:prednisolon; use of vitamins and anti oxidants 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 syndromeStein-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 malondealdehyde
Timepoint
before intervention and after intervention on the oocyte collection day
Method of measurement
American key man kit

2

Description
serum total antioxidant capaity(TAC)
Timepoint
before intervention and after intervention on the oocyte collection day
Method of measurement
American key man kit

3

Description
serum super oxid dismuthase
Timepoint
before intervention and after intervention on the oocyte collection day
Method of measurement
American key man kit

4

Description
follicular fluid malondealdehyde
Timepoint
on the oocyte collection day
Method of measurement
American key man kit

5

Description
follicular fluid total anti oxidant capacity

Timepoint
on the oocyte collection day
Method of measurement
American key man kit

6

Description
follicular fluid super oxid dismuthase
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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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