

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of vitamin E in a couple with unexplained infertility on embryo quality and outcome of IVF

Protocol summary

Summary

The overall objective: Evaluation of the effect of vitamin E on quality of embryo and ovum in invitro fertilization in unexplained infertility. Specific goals: - Compare motility of sperm in semen analysis before and after vitamin E in two groups of case and control-- Compare normal shape of sperm in semen analysis before and after vitamin E in two groups of case and control-- Compare count of sperm in semen analysis before and after vitamin E in two groups of case and control-- Compare Total Motile Sperm Count of sperm in semen analysis before and after vitamin E in two groups of case and control -- Effect of vitamin E in number of ovum in IVF--Effect of vitamin E in quality of ovum in IVF--Effect of vitamin E in number of embryo in IVF--Effect of vitamin E in quality of embryo in IVF-- Compare the people with positive Human Chorionic Gonadotropine in case and control groups-- Compare the people with positive Fetal heart rate in case and control groups- Materials and methods: 120 couple of patient with unexplained infertility(normal semen analysis and normal ovulation and normal tubes and endometrial cavity)that candidate for IVF in Madar koodak clinic of infertility of Ghadir came to our study. according to consult with statistic the patient divided to two groups 60 patient for case and 60 patient for control. Drug (400 mg vitamin E) and placebo prepared by pharmacologist with the same shape. and the patient have the package of drug due to number of coming to study drugs melatonin or placebo have the same packages and special code. each person including the study such as gynecologist, resident or staff of infertility clinic do not know each packet is vitamin E or placebo and our study is completely double-blind. the patient eat drug or placebo 2 month and IVF was done and semen analysis repeat, data complete in proposal and then code of drug packets will be opened. and two groups compare with each other

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405286541N4**

Registration date: **2014-07-14, 1393/04/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-14, 1393/04/23

Registrant information

Name

Bahia Namavar Jahromi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1233 2365

Email address

namavarb@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University Of Medical Science

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamine E in a couple with unexplained infertility on embryo quality and outcome of IVF

Public title

Effect of vitamin E in out come of IVF

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: Normal semen sample : Normal Hystrosalpin geography : Normal ovulation: IVF For ferst time : Long protocole! Befor 39 years old : Inclusion criteria: No desire for cooperation : Sensivity to Vitamin E $39 \leq$: year old :

Age

From **18 years** old to **39 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Medical Science Researching, Shiraz Univercity of Medical Science

Street address

Shiraz University Of Medical Sciences

City

Shiraz

Postal code

Approval date

2014-03-16, 1392/12/25

Ethics committee reference number

CT-P-92-5856

Health conditions studied

1

Description of health condition studied

- Unexplained infertility

ICD-10 code

N97.9

ICD-10 code description

Female linfertility, Unspecified

Primary outcomes

1

Description

- Quality and number of ovum and emberyo have received in each IVF cycle

Timepoint

- On day of ovum pick up and emberyo insercion (IVF)

Method of measurement

- Measuring number and quality of ovumes on the day of pick up in lab by pathologist under microscope (GV , MI , MII) and quality of emberyo also by the same pathologist due to kind of cell division (Grade I , II , III , IV)

Secondary outcomes

1

Description

Clinical pregnancy or misscariage

Timepoint

4 - 6 weeks after emberyo transferring

Method of measurement

Serum BHCG and TVS

Intervention groups

1

Description

In The Main Group The paitents eats one ca of vitaminE or placebo (400mg) one per day from the day of base sono till 2 month

Category

Treatment - Drugs

2

Description

In The control group The Patients eats one ca of vitaminE or placebo (400mg) one per day from the day of base sono till 2 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mother & Child Hospital,Shiraz

Full name of responsible person

Dr Zahra Mosallanezhad

Street address

Shiraz University of Medical Sciences , Zand Street

City

Shiraz

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street addressShiraz University of Medical Sciences, Zand Street,
Shiraz**City**

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Zahra Mosallanezhad

Position

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s.kharati@yahoo.com**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr Bahia Namavar Jahromi

Position

Professor of Obstetrics & GYN, Fellowship Infertility

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s.kharati@yahoo.com**Web page address****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