Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assess of effect of oral vitamin E on increase of In Vitro Fertilization success in infertile men

Protocol summary

Summary

120 of the patients who have been candidated for IVF, due to male infertility, in Infertility center of Ghadir Mother and Child Hospital will be studied. 60 of those people will be placed in case group and the other 60 will be placed in control group. Pharmacist Physician will prepare and encode the pharmacy package, contains 400IU of vitamin E and placebo identically, such away that its appearance is quite similar and look indistinguishable for the executive and patients. Patients will recieve the pharmacy package coded from the pharmacologist; according to the table given by pharmacologists,depending on their enterance time to the project. Each patient will use the pharmacy package for two months and then th sperm analysis will be performed. Then, the IVF procedures will be done and the data will be recorded in the questionaires attached and will be stored in SPSS software. After gathering data and entering it in the system, the codes will be broken and statistical analysis will be performed between the Case and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020616506N1**
Registration date: **2014-03-18, 1392/12/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-03-18, 1392/12/27

Registrant information

Name
Niloofar Borzou

Name of organization / entity
Shiraz University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 71 1227 9715

Email address
borzou@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences- Vice Chancellor for research

Expected recruitment start date

2014-05-01, 1393/02/11

Expected recruitment end date

2016-12-27, 1395/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assess of effect of oral vitamin E on increase of In Vitro Fertilization success in infertile men

Public title

Assess of effect of oral vitamin E on increase of In Vitro Fertilization success in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion conditions: 120 of the patients who have been candidated for IVF due to male infertility, have been diagnosed through the semen analysis upon WHO's criteria and have satisfied the conditions of performing IVF based on existing criteria (i.e. after semen processing, it contains less than 1-2 million motile

sperms, or less than 10 million motile sperms in addition to more than 2 years infertility without any response to IUI) will be studied. Exclusion conditions: If people are not willing to cooperate in the project or consuming vitamin E, for any reason and also show any sensitivity to vitamin E, will be excluded from the project.

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

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

Shiraz University of Medical Sciences- Vice Chancellor for research

Street address

Iran- Fars- Shiraz- Zand street- Central department- Shiraz University of Medical Sciences- Vice Chancellor for research

City

Shiraz

Postal code

Approval date

2013-12-24, 1392/10/03

Ethics committee reference number

CT-P-92-5604

Health conditions studied

1

Description of health condition studied

Male infertility

ICD-10 code

N46

ICD-10 code description

Oligospermia NOS

Primary outcomes

1

Description

Comparison of sperm counts

Timepoint

After two mounts of treatment

Method of measurement

Semen analysis

2

Description

Comparison of sperm motility

Timepoint

After two mounts of treatment

Method of measurement

Semen analysis

3

Description

Comparison of the percentage of normal shape sperm

Timepoint

After two mounts of treatment

Method of measurement

Semen analysis

Secondary outcomes

1

Description

Comparison of clinical pregnancy rate

Timepoint

6-8 weeks after IVF

Method of measurement

By follow up of the patients and sonography

2

Description

Comparison of chemical pregnancy rate

Timepoint

16-18 days after IVF

Method of measurement

By measurement of B-HCG

Intervention groups

1

Description

Interventiion group: 400 IU Vit E will be given orally to 60 infertile men for two months before IVF.

Category

Treatment - Drugs

2

Description
Control group: similar shape placebo will be given orally to 60 infertile men two months before IVF.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghadir Mother & Child Hospital, infertility ward
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences- Vice Chancellor for research
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Iran- Fars- Shiraz- Zand street- Central department- Shiraz University of Medical Sciences- Vice Chancellor for research
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- Vice Chancellor for research
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 Scienses
Full name of responsible person
Niloofar Borzou
Position
Extern, Medical student
Other areas of specialty/work
Street address
Iran, Shiraz, Shahid Faghihi Hospital, Department of OB-GYN
City
Shiraz
Postal code
Phone
+98 71 1227 9715
Fax
Email
borzou@sums.ac.ir
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
Other areas of specialty/work
Street address
Department of OB-GYN, Shahid Faghihi Hospital, Shiraz, Iran.
City
Shiraz
Postal code
Phone
+98 71 1227 9715
Fax
Email
namavarb@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Scienses
Full name of responsible person
Niloofar Borzou
Position
Extern, Medial student
Other areas of specialty/work
Street address
Iran- Shiraz-Faghihi Hospital-Department of OB-GYN
City
Shiraz
Postal code
Phone
+98 71 1227 9715
Fax
+98 71 1227 9715
Email
Borzou@sums.ac.ir

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