

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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 entrance 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 questionnaires 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

Niloofer Borzou

Name of organization / entity

Shiraz University of Medical Science

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Iran (Islamic Republic of)

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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**

Intervention 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

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

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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 Sciences

Full name of responsible person

Niloofar Borzou

Position

Extern, Medical student

Other areas of specialty/work

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty