

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

assess of effect of oral vitamin E on increase of intra uterine insemination success in infertile men

Protocol summary

Summary

120 cases of patients with male infertility who will be detected by semen fluid analysis on the basis of WHO criteria and also are candidate for IUI will be studied. 60 cases will be in control group and another 60 cases in the case group. Pharmacist physician will make an encoded packages containing 400IU vitamin E and placebo quite similar to each other so that they will be indistinguishable to both executive and the patients. Patients will receive encoded packages on the basis of the order based on the plan table offered by the pharmacologist. Each patient will receive the package content for two months and the sperm analysis and after that the routine steps of IUI will be done. And information will be embedded in the questionnaire after collecting data. Then the codes of the packages will be broken and statistical analysis will be done between the case and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122815961N1**

Registration date: **2014-04-24, 1393/02/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-04-24, 1393/02/04

Registrant information

Name

faranak fatehpour

Name of organization / entity

shiraz university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 71 1227 9715

Email address

fatehpoorf@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 intra uterine insemination success in infertile men

Public title

assess of effect of oral vitamin E on increase of intra uterine insemination success in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Sperm count less than or equal to 15000000 CC : progressive motility less than or equal to 32%: normal shaped sperm less than or equal to 4% according to WHO 2011 criteria for male infertility : doing IUI for the first time Exclusion criteria : not willing to cooperate in the project : not willing to use vitamin E for any reason : showing sensitivity to vitamin E

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: **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**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**

2013-12-18, 1392/09/27

Ethics committee reference number

CT-P-92-5605

Health conditions studied**1****Description of health condition studied**

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes**1****Description**

sperm counts

Timepoint

After two mounts of treatment

Method of measurement

Semen analysis

2**Description**

sperm motility

Timepoint

After two mounts of treatment

Method of measurement

Semen analysis

3**Description**

percentage of normal shape sperm

Timepoint

After two mounts of treatment

Method of measurement

Semen analysis

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

clinical pregnancy rate

Timepoint

6-8 weeks after IVF

Method of measurement

By follow up of the patients and sonography

2**Description**

chemical pregnancy rate

Timepoint

16-18 days after IVF

Method of measurement

By measurement of B-HCG

Intervention groups**1****Description**Interventiion: 400 IU Vit E will be given orally to 60
infertile men for two months before IUI.**Category**

Treatment - Drugs

2**Description**control: Similar shape placebo will be given orally to 60
infertile men two months before IUI.**Category**

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother & Child Hospital, infertility ward

Full name of responsible person

faranak Fatehpour

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 Sciences

Full name of responsible person

Faranak Fatehpour

Position

Extern

Other areas of specialty/work

Street address

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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

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Person responsible for updating data

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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