

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effects of folic acid, vitamin E, selenium on semen parameters in infertile men

Protocol summary

Summary

The aim of this study is to evaluate the effect of folic acid, Vitamin E and selenium on the number, motility, morphology of sperms and white cells in the semen of men with idiopathic infertility. 70 of the men who are suffering with idiopathic infertility and recourse to infertility center of Ghadir hospital and outpatient clinics of Shiraz University of Medical Sciences and During two consecutive analyzes at least one of the sperm parameters was impaired and during laboratory and radiological investigations, no anatomical and hormonal disorder diagnosed are enrolled in this study. According to The method of random block permutation participants assigned to two experimental and control groups. Then all samples are taught that do not have intercourse for 3 to 5 days and go for testing. Patients are recommended for masturbation method collect semen in a clean container and not having intercourse to collect semen sample because of the risk of contamination. After 24 hours the test report is provided. And if researchers desired parameters are disrupted (patients who have inclusion criteria) for 12 weeks daily 5mg tablet of folic acid Galinuse, 200 mcg tablets selenium Nature Med and 400 IU vitamin E Zahravi are given to the experimental group and in this period participants in control group are given placebo. During these 12 weeks patients are evaluated with a phone call about how to eat supplements. At the end of 12 weeks analysis will be repeated and difference before and after intervention in both groups as well as between the two study and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012432153N1**

Registration date: **2017-06-17, 1396/03/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-17, 1396/03/27

Registrant information

Name

Rezvan Bahmyari

Name of organization / entity

School of Nursing and Midwifery, Shiraz

Country

Iran (Islamic Republic of)

Phone

+98 77 3312 5676

Email address

stud35300572232@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences Dr Basir Hashemi

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of folic acid, vitamin E, selenium on semen parameters in infertile men

Public title

Effect of folic acid, vitamin E, selenium on semen parameters

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria:Tendency to participate in the study;
Age range 25 to 54 years; Do not use of micronutrients out of study; Rejection of any obstructive disorder during radiological studies and anatomical examination;
Abnormal parametres be approved by two semen analysis within two weeks exclusion criteria: lake of Tendency to participate in the study; Azoospermia or Aspermia men; Men with sever varicocele; Recent urogenital infection that have been treated with antioxidants; History of allergic reactions to micronutrients; treated with the following drugs: sulfasalazine- methotrexate-Nitrofurantoin -colchicine -alpha blockers and cimetidine - spironolactone- antidepressants, beta-blocker-phenothiazine- metoclopramide-heroin- cocaine-cannabis-thiazide diuretic

Age
From **25 years** old to **54 years** old

Gender
Male

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)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethic committee of Shiraz University of Medical Sciences

Street address
No 60 ,Zand street, Shiraz University of Medical

Sciences,Shiraz, Iran

City
Shiraz

Postal code
Iran

Approval date
2017-01-08, 1395/10/19

Ethics committee reference number
IR.SUMS.REC.1395.160

Health conditions studied

1

Description of health condition studied
male infertility

ICD-10 code
N46

ICD-10 code description
Azoospermia NOS - Oligospermia NOS

Primary outcomes

1

Description
sperm morphology

Timepoint
Before intervention ninety days after intervention

Method of measurement
semenal analysis

2

Description
Sperm count

Timepoint
Before and ninety days after intervention

Method of measurement
semenal analysis

3

Description
Sperm motility

Timepoint
Before and ninety days after intervention

Method of measurement
semenal analysis

4

Description
White blood cell count

Timepoint
Before and ninety days after intervention

Method of measurement
semenal analysis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Daily intake of 200 micrograms of selenium tablets nature med Manufacturing Co., 400 IU of vitamin zahravi Manufacturing Co. i, 5 mg folic acid tablets Galinuse Manufacturing Co. , once-daily, orally for 12 weeks

Category

Treatment - Drugs

2

Description

control group:Placebo daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

former mother and child hospital

Full name of responsible person

Azima sara

Street address

İNo 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street address

No 60 ,Zand Street, Shiraz University of Medical Sciences,Shiraz,Iran

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of 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

School of Nursing and Midwifery, Shiraz

Full name of responsible person

Azima Sara

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work

Street address

İNo 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 71 3647 4254

Fax

Email

azimas@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery, Shiraz

Full name of responsible person

Azima Sara

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work

Street address

İNo 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran

City

Shiraz

Postal code

Phone

+98 71 3647 4254

Fax

+98 36474252

Email

Azimas@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Department of midwifery ,School of Nursing and Midwifery,Shiraz University of Medical Sciences, Shir

Full name of responsible person

Azima Sara

Position

Master's degree in Midwifery, Faculty member

Other areas of specialty/work**Street address**

ÍNo 73,School of Nursing and Midwifery,Nemazee
squair, Shiraz, Iran

City

Shiraz

Postal code

Iran

Phone

+98 71 3647 4254

Fax

+98 36474254

Email

Azimas@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