Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of supplement therapy and antioxidant on spermogram in Varicocelectomized infertile men with varicoceles

Protocol summary

Summary

This study aimed to investigate the effect of therapeutic and antioxidant supplements on spermogram in infertile men with varicocele after varicocelectomy.The statistical population of this study includes all infertile men with clinical varicoceles who referred to Semnan Kosar Hospital in 2015-2016. evaluations including medical history, clinical examination, and at least two semen analyses .The participants were included in the study based on the inclusion and exclusion criteria. Incusion criteria: Full satisfaction from participation in the scheme;a medical history of primary or secondary infertility with at least one year of regular unprotected sexual intercourse. The exclusion criteria: Men have wives with ovulatory disorder (infertile); female infertility caused by pelvic disorders (endometriosis or adhesion). The sample is divided into two groups: Intervention group and control group. The patients were selected by single-blind balanced (permuted) block randomization method. Patients undergone a varicocelectomy repair with inguinal or sub inguinal approach. Intervention group received 200 mcg selenium supplements, 5mg folic acid and 400IU of vitamin E per day for 3to 6 months.Control group was given neither of the supplements. Based on statistical formula, there are 30 participants in each group. After 3 to 6 months of intervention, the results of spermogram and participants' fertility were analyzed and recorded on a researcher made checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091223855N2**
Registration date: **2015-10-29, 1394/08/07**
Registration timing: **na**
Last update:
Update count: **0**

Registration date

2015-10-29, 1394/08/07

Registrant information

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Recruitment status

Not enough for processing

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-09-21, 1394/06/30

Expected recruitment end date

empty

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplement therapy and antioxidant on spermogram in Varicocelectomized infertile men with varicoceles

Public title

effect of supplement therapy and antioxidant therapy on spermogram after varicocelectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with varicocele at least two semen fluid analysis done with the full consent for their participation in the project , and with a history of primary or secondary infertility for at least one year . Exclusion criteria: patients who have a spouse with ovulatory dysfunction (infertile) and suspected infertility due to pelvic disorders (endometriosis or adhesions there)

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Department of Medical Sciences, Basij Blvd, Semnan, Iran

City

Semnan

Postal code

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

IR.SEMUMS.REC.1394.71

Health conditions studied

1

Description of health condition studied

varicocele

ICD-10 code

186.1

ICD-10 code description

Scrotal varices

Primary outcomes

1

Description

spermogram

Timepoint

Before the intervention and after intervention

Method of measurement

Spermogram

Secondary outcomes

empty

Intervention groups

1

Description

Control group:after varicocellectomy the patients will be observed and wont recieved any drugs for 3-6 months .

Category

Treatment - Drugs

2

Description

Intervention group:After surgery, the Interventionl group will be treated with 200 micrograms of selenium supplementation per day and 5 mg of folic acid a day and 400 IU per day of antioxidant vitamin E for 3 to 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital Center

Full name of responsible person

Dr Davood Drab

Street address

Kosar Hospital, Basij BLVd, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice- Chancellor in Research Affairs(Semnan University of Medical Sciences)

Full name of responsible person
Dr Ali Rashidipour
Street address
Department of Medical Sciences, Basij Blvd, semnan
City
Semnan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice- Chancellor in Research Affairs(Semnan 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

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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