

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of Zinc sulfate and Folic acid administration on semen quality and some sex hormones in varicocelectomized men

Protocol summary

Summary

Varicocele is a common disease of male genital organ that may cause subfertility or infertility. Folic acid and zinc sulfate have been introduced as treatments in the case of subfertility in infertility causative factors other than varicocele. Our aim of this study is to investigate the probable effects of folic acid and zinc sulfate on semen quality and fertility status of male subjects undergoing varicocelectomy. One hundred Patients suffering from varicocele will be randomly divided to four groups of 25 patients each. Patients will receive appropriate surgery to correct the varicocele. Following varicocelectomy, Patients will receive zinc sulfate, folic acid, zinc sulfate and folic acid, or placebo respectively. Patients with a history of Diabetes, high blood pressure and cancer of testis will be excluded. Hormonal status (Tetosterone, FSH and Inhibin), semen and sperm parameters, and the level of NO and SOD will be evaluated before the intervention, three and six months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802261910N1**

Registration date: **2009-09-26, 1388/07/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-09-26, 1388/07/04

Registrant information

Name

Seyed Nouredin Nematollahi Mahani

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

nnematollahi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Science

Expected recruitment start date

2008-02-29, 1386/12/10

Expected recruitment end date

2009-12-28, 1388/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Zinc sulfate and Folic acid administration on semen quality and some sex hormones in varicocelectomized men

Public title

Effect of zinc and folic acid on male reproduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Men with a history of varicocele.

Exclusion criteria: Men with a history of cancer of testis, high blood pressure (systolic blood pressure >140 mmHg), or diabetes.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kerman University of Medical Science

Street address

Tahmasb abad cross, chancelor in research

City

kerman

Postal code

Approval date

2006-01-25, 1384/11/05

Ethics committee reference number

K/85/64

Health conditions studied

1

Description of health condition studied

varicocele

ICD-10 code

I86.1

ICD-10 code description

Scrotal varices

2

Description of health condition studied

Male infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Change in sex hormone

Timepoint

Before intervention, 3 mo, and 6 mo after intervention

Method of measurement

Evaluation of hormones by ELIZA

2

Description

Quality of semen

Timepoint

Before intervention, 3 mo, and 6 mo after intervention

Method of measurement

sperm analysis

Secondary outcomes

1

Description

Change in fertility status

Timepoint

1 y

Method of measurement

Rise in hCG/ sonographic evaluation

Intervention groups

1

Description

Folic acid Capsules 5 mg/day, orally plus Zinc sulfate 50 mg/day orally for six months

Category

Treatment - Drugs

2

Description

Zinc sulfate Capsules 50 mg/day, orally plus placebo capsules with the same dose and shape as Folic acid capsules for 6 months

Category

Treatment - Drugs

3

Description

Folic acid Capsules 5 mg/day, orally plus placebo capsules with the same dose and shape as Zinc sulfate capsules for 6 months

Category

Treatment - Drugs

4

Description

Placebo capsules filled with starch with the same dose and shape as active drugs (Folic acid and Zinc sulfate capsules) for 6 months

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Shafa hospital/ private clinic

Full name of responsible person

A Azizollahi, MD.

Street address**City**

kerman

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

H Najafipour, Ph.D.

Street address

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City

Kerman

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Seyed Nouredin Nematollahi-mahani

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Ph.D/ Academic staff

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Associate prof/Ph.D.

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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