

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effectiveness of zinc supplement on spermogram of sub fertile men.

Protocol summary

Summary

Objective: To study the effects of zinc sulfate treatment on semen variables in fertile and subfertile men. Design: Double-blind, placebo-controlled interventional study. Setting: The study comprised one hundred twenty sub fertile men who referred Akbar Abadi hospital, infertility center and one outpatient infertility clinic, Tehran, Iran. Intervention(s): total sperm count in these patients is 5000000 to 20000000; also we measured plasma zinc and semen zinc concentration. Patients were randomly allocated to treatment with Zinc supplement (n = 60) was given 10 ml three times a day and placebo (n = 60) with the same order. After three months we will recheck sperm count and plasma zinc and semen zinc and will analyzed them. Main inclusion criteria: subfertile men with sperm concentration 5000000 to 20000000; main exclusion criteria: known chromosomal abnormality related to infertility. Main Outcome Measure(s): sperm concentration, plasma zinc, semen zinc.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041120923N2**

Registration date: **2016-01-18, 1394/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-18, 1394/10/28

Registrant information

Name

Fatemeh Sharifzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Iran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of zinc supplement on spermogram of sub fertile men.

Public title

Zinc supplement effect on sperm count.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Subfertile men as defined failure of the female partner to conceive after 1 year of regular, unprotected intercourse; sperm concentration of 5 and 20 million on the semen analysis. Exclusion criteria: Abnormal endocrine screening(hypo or hyper thyroidemia); Men with chromosomal disorder such as Y chromosome deletions; use of zinc or other supplements in the 3 months before recruitment.

Age

From **20 years** old to **50 years** old

Gender

Male

Phase

2

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

sealed envelope

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2015-07-21, 1394/04/30

Ethics committee reference number

IR.IUMS.REC.1394.26155

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 Concentration

Timepoint

Prior to intervention, 3 months after intervention

Method of measurement

Sperm Analysis, Million/ml

2

Description

Serum Zinc

Timepoint

Prior to intervention, 3 months after intervention

Method of measurement

Serum Biochemistry Test/ Micro gr/ dl

3

Description

Semen Zinc

Timepoint

Prior to intervention, 3 months after intervention

Method of measurement

Semen Biochemistry Test, mg/dl

Secondary outcomes

1

Description

Sperm Morphology

Timepoint

Prior to intervention, 3 months after intervention

Method of measurement

Sperm Analysis, Percent

2

Description

Sperm Motility

Timepoint

Prior to intervention, 3 months after intervention

Method of measurement

Sperm Analysis, Percent

Intervention groups

1

Description

Intervention group 2: Water Soluble/ 10 cc/ 3 times a day

Category

Placebo

2

Description

Intervention group 1: Zinc Soluble Alhavi, 0.5%/ 10cc/ 3 times a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Akbar Abadi Infertility Center
Full name of responsible person
Sara Norouzi
Street address
Shahid Akbar Abadi Hospital, Molavi Ave
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Tehran

Fax
Email
Sr.norouzi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Fatemeh Sharifzadeh
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Assistant Professor
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research Of Iran University of Medical Sciences
Full name of responsible person
Dr Seid Ali Javad Mousavi
Street address
Iran University of Medical Sciences, Shahid Hemmat highway
City
Tehran
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 Iran 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
Iran University of Medical Sciences
Full name of responsible person
Sara Norouzi
Position
resident of obstetrician & gynecology
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Person responsible for updating data

Contact

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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