

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Zinc and Folic Acid on sperm function test in infertile men

Protocol summary

Summary

The aim of this study was to investigate the role of folic acid and zinc sulfate supplementation on improvement of sperm functions among infertile male with oligoasthenoteratozoospermia but not anatomical and other impotency cases. Four groups of 25 infertile men including groups supplemented with Folic acid/Zinc, Folic acid/ placebo, Zinc/placebo and placebo/placebo to demonstrate the effect of individual supplement in fertility and sperm function tests. Intervention include above 4 experiment modes of supplementation. 16 weeks after treatment; semen analysis and sperm function test were measured as primary outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706091079N2**
Registration date: **2011-07-18, 1390/04/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-18, 1390/04/27

Registrant information

Name

Mohammad Reza Sadeghi

Name of organization / entity

Avicenna Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2024

Email address

sadeghi@avicenna.ac.ir

Recruitment status

Recruitment complete

Funding source

Iranian Academic Center for Education ,Culture and Research (ACECR)

Expected recruitment start date

2007-05-31, 1386/03/10

Expected recruitment end date

2008-10-01, 1387/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zinc and Folic Acid on sperm function test in infertile men

Public title

Effect of Zinc and Folic Acid on semen analysis and sperm function

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria:infertile men with oligoasthenoteratozoospermia, 20-45 years old exclusion criteria: men with severe and chronic underlying disease such as dibet, SC disabilities.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

2-3

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

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Research Institute

Street address

Avicenna Research Institute, Shahid Beheshti
University, Evin, Tehran, Iran

City

Tehran

Postal code

1983969411

Approval date

2006-11-21, 1385/08/30

Ethics committee reference number

85/3496

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 function test

Timepoint

before treatment commence and 16 weeks after
treatment

Method of measurement

sperm function tests according to WHO standard

2

Description

semen analysis

Timepoint

before treatment commence and 16 weeks after

treatment

Method of measurement

routine semen analysis according to WHO standard

Secondary outcomes

1

Description

total antioxidant capacity (TAC)

Timepoint

16 weeks after treatment

Method of measurement

spectrophotometry

2

Description

reactive oxygen species (ROS)

Timepoint

16 weeks after treatment

Method of measurement

chemiluminescence

Intervention groups

1

Description

Zinc / placebo Zinc; 220 mg/day, Oral Route, 16 weeks
duration Placebo; 5 mg/day, Oral Route, 16 weeks
duration

Category

Treatment - Drugs

2

Description

Folic acid / placebo Folic acid; 5 mg/day, Oral Route, 16
weeks duration Placebo; 220 mg/day, Oral Route, 16
weeks duration

Category

Treatment - Drugs

3

Description

Folic acid / Zinc Folic acid; 5 mg/day, Oral Route, 16
weeks duration Zinc; 220 mg/day, Oral Route, 16 weeks
duration

Category

Treatment - Drugs

4

Description

placebo / placebo Placebo; 5 mg/day, Oral Route, 16
weeks duration Placebo; 220 mg/day, Oral Route, 16
weeks duration

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Avicenna Infertility Clinic

Full name of responsible person

Mohammad Reza Sadeghi

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No 97, Yakhchal and Shariati Ave Cross, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Academic Center for Education and Culture and Research

Full name of responsible person

Mohammad Reza Sadeghi

Street address

No 1270, Enghelab Avenue, Tehran, Iran

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Tehran

Grant name

113620

Grant code / Reference number

1212-22

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

Yes

Title of funding source

Academic Center for Education and Culture and 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

Avicenna Research Institute

Full name of responsible person

Mohammad Reza Sadeghi

Position

associate professor / Ph.D.

Other areas of specialty/work

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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