

# 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

**Street address**

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

**City**

Tehran

## 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

**City**

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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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*