

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Ubiquinone Supplementation on Semen Quality, Antioxidant Enzyme, Oxidative Stress and DNA Fragmentation in infertile men

#### Protocol summary

##### Summary

The present study was designed to determine the effects of CoQ10 supplementation on semen quality, seminal antioxidant enzymes, oxidative stress, and sperm DNA fragmentation in idiopathic oligoasthenoteratozoospermic men referring to Avicenna infertility Clinic. In a randomized placebo-controlled trial, 60 infertile men aged between 20-50 years with idiopathic oligoasthenoteratozoospermia and at least 1 year history of infertility selected. They were excluded if they had infectious genital disease, anatomic abnormality of genital tract, occupational chemical exposure, history of genital tract surgery, or they used drug and antioxidant supplement within the 3 months before enrollment in the present study. The enrolled patients underwent dietary implementation of CoQ10 100 mg twice daily (200 mg) or placebo For 3 months. Seminal plasma superoxide dismutase, Glutathione peroxidase, and Glutathione reductase, TAC, Level of Isoprostane, Sperm DNA fragmentation and Ubiquinone concentration were assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138706031079N1**

Registration date: **2011-08-09, 1390/05/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-08-09, 1390/05/18

##### 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

Avicenna Research Institute, Tehran medical sciences university

##### Expected recruitment start date

2008-07-31, 1387/05/10

##### Expected recruitment end date

2009-08-01, 1388/05/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Ubiquinone Supplementation on Semen Quality, Antioxidant Enzyme, Oxidative Stress and DNA Fragmentation in infertile men

##### Public title

Co Q10 and Semen parameter

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion : idiopathic oligoasthenoteratospermia, normal profile for hormones, normal genital anatomy Exclusion: major infection in genital organ, treatment for systemic disease during the last three months of inclusion, surgery background on genitalia, exposure to chemicals ,solvents or heavy metals, supplementation therapy in last three

months of inclusion

**Age**

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

**Gender**

Male

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**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

**City**

Tehran

**Postal code**

1983969411

**Approval date**

2008-09-03, 1387/06/13

**Ethics committee reference number**

87.3003

**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**

semen analysis

**Timepoint**

45 days , 90days

**Method of measurement**

HPLC, flourometry , spectrophotometry, ELIZA

2

**Description**

sperm Isoprostan concentration

**Timepoint**

45 days , 90days

**Method of measurement**

ELIZA

3

**Description**

activity of seminal plasma catalase

**Timepoint**

45 days , 90days

**Method of measurement**

spectrophotometry

4

**Description**

activity of seminal plasma superoxide dysmutase

**Timepoint**

45 days , 90days

**Method of measurement**

spectrophotometry

5

**Description**

seminal plasma ubiquinone concentration

**Timepoint**

45 days , 90days

**Method of measurement**

HPLC

6

**Description**

DNA fregmentation

**Timepoint**

45 days , 90days

**Method of measurement**

Flowcytometry

**Secondary outcomes**

1

**Description**

seminal plasma glutathion peroxidase

**Timepoint**

45 days, 90 days

**Method of measurement**

spectrophotometry

## 2

### **Description**

seminal plasma glutathion reductase

### **Timepoint**

45 days, 90 days

### **Method of measurement**

spectrophotometry

## 3

### **Description**

Total Antioxidant Capacity(TAC)

### **Timepoint**

45 days, 90 days

### **Method of measurement**

spectrophotometry

## 4

### **Description**

seminal plasma Coenzyme Q10

### **Timepoint**

45 days, 90 days

### **Method of measurement**

HPLC

## **Intervention groups**

## 1

### **Description**

Co Q10 supplement: 2 (100 mg) per day (200 mg), 3 month,

### **Category**

Treatment - Drugs

## 2

### **Description**

Placebo (lactose): 2 capsule per day, 3 month

### **Category**

Treatment - Drugs

## **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

#### **City**

Tehran

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Avicenna Research Institute; Tehran Medical Sciences University

#### **Full name of responsible person**

Mohammad Reza Sadeghi

#### **Street address**

Avicenna Research Institute, Shahid Beheshti University, Evin, Tehran; Tehran Medical Science University, Crossing of Chamran and Hemmat highways, Tehran

#### **City**

Tehran

#### **Grant name**

113641

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Avicenna Research Institute; Tehran Medical Sciences University

#### **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 Resaerch Institute

#### **Full name of responsible person**

Mohammad Reza Sadeghi

#### **Position**

Associate professor / Ph.D.

#### **Other areas of specialty/work**

#### **Street address**

Avicenna Research Institute, Shahid Beheshti University , Evin, Tehran

#### **City**

Tehran

#### **Postal code**

1983969411

#### **Phone**

+98 21 2243 2024

#### **Fax**

+98 21 2243 2021

#### **Email**

sadeghi@avicenna.ac.ir

#### **Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Avicenna Research Institute

**Full name of responsible person**

Mohammad Reza Sadeghi

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Associate Professor / Ph.D.

**Other areas of specialty/work**

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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*