Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 oligoasthenoteratozospermic men referring to Avicenna infertility Clinic. In a randomized placebo-controlled trial, 60 infertile men aged between 20-50 years with idiopathic oligoasthenoteratozoosperia 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 gluthation peroxidase

Timepoint
45 days, 90 days

Method of measurement

spectrophotometry

2

Description
seminal plasma gluthation 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

www.avicenna.ac.ir

Person responsible for scientific 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

Street address
Avicenna Research Institute, Shahid Beheshti University , Evin

City
Tehran

Postal code
1983969411

Phone
+98 21 2243 2024

Fax
+98 21 2243 2021

Email
sadeghi@avicenna.ac.ir

Web page address
www.avicenna.ac.ir

Person responsible for updating data

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

Street address
Avicenna Research Institute, Shahid Beheshti University, Evin, Tehran.

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Phone
+98 21 2243 2024

Fax
+98 21 2243 2021

Email
sadeghi@avicenna.ac.ir

Web page address
www.avicenna.ac.ir

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