

Effects of coenzyme Q10 (CoQ10) supplementation on semen quality and seminal oxidative stress of idiopathic oligoasthenoteratozoospermic (iOAT) infertile men

Submission date 05/10/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/12/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/05/2012	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Avicenna Research Center Ref: 5405/20/28PY (registered on 28/01/2008)

Study information

Scientific Title

Effects of three-month supplementation with 200 mg of ubiquinone (coenzyme Q10 [CoQ10]) on semen quality, antioxidant enzymes of seminal plasma, sperm DNA fragmentation, total antioxidant capacity and isoprostane of seminal plasma in idiopathic oligoasthenoteratozoospermic infertile men: a double-blind randomised placebo-controlled trial

Study objectives

The ubiquinone supplementation will:

1. Increase sperm motility
2. Increase the percent of normal sperms
3. Increase curvilinear velocity of sperm
4. Increase straight progressive velocity of sperm
5. Decrease 15-2 alpha isoprostane in seminal plasma
6. Increase total antioxidant capacity of seminal plasma
7. Decrease sperm DNA fragmentation
8. Increase catalase activity in seminal plasma
9. Increase super oxide dismutase activity in seminal plasma
10. Increase glutathione peroxidase activity in seminal plasma
11. Increase ubiquinone concentration in seminal plasma

Ethics approval required

Old ethics approval format

Ethics approval(s)

Avicenna Ethics Committee, approved on 10/03/2008 (ref: 6191/51/28PY)

Primary study design

Interventional

Study design

Double-blind randomised placebo-controlled single-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Male infertility

Interventions

The participants will be randomly allocated to the following two arms (randomisation ratio 1:1):

Intervention group: 100 mg ubiquinone capsule (oral) (Pharmed Int. Inc., Canada) twice daily with lunch and dinner for 3 months

Control group: Placebo (lactose powder) in similar capsules twice daily for 3 months

Total duration of follow-up: 90 days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ubiquinone (coenzyme Q10)

Primary outcome(s)

1. Super oxide dismutase and glutathione peroxidase activity of seminal plasma and 15-F2 alpha isoprostane concentration will be measured by commercial kits
2. Catalase activity of seminal plasma
3. Total antioxidant capacity of seminal plasma
4. Concentration of ubiquinone in seminal plasma will be measured by High Performance Liquid Chromatography (HPLC) at baseline and 3 months
5. Dietary intake will be assessed by 3 days dietary recall at baseline, 45 days and 3 months and will be analysed by nutrition analysis software (Food Processor II)

All primary outcomes will be assessed at baseline and 3 months

Key secondary outcome(s)

1. Sperm morphology and motility will be assessed with spermiogram in accordance with the WHO 1999 criteria and also by computer-assisted sperm analysis
2. Sperm DNA fragmentation will be measured by Sperm Chromatin Structure Analysis (SCSA)

All secondary outcomes will be assessed at baseline and 3 months

Completion date

01/10/2009

Eligibility

Key inclusion criteria

1. Men 20-45 years
2. With idiopathic oligoasthenoteratozoospermia (sperm count $5-20 \times 10^6/\text{mL}$, sperm motility according to World Health Organization (WHO) 1999 criteria $<50\%$ and normal sperm morphology $<30\%$)
3. Seminal white blood cells $<1 \times 10^6/\text{mL}$
4. At least 1 year of infertility
5. Normal serum levels of gonadotropines, testosterone and prolactine
6. Absence of systemic diseases, treatment with drug or supplement use in the 3 months before enrolment
7. Absence of infectious genital disease and anatomical abnormalities of the genital tract
8. Absence of smoking, drug addiction or alcohol consumption
9. Absence of occupational chemical exposure
10. Absence of surgical history on testis or vasodeferane

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Discontinuation in supplement usage.

Date of first enrolment

01/10/2008

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

Iran

Study participating centre

Avicenna Research Institute (ARI)

Tehran

Iran

19615

Sponsor information

Organisation

Iran University of Medical Sciences (Iran)

ROR

<https://ror.org/03w04rv71>

Funder(s)

Funder type

University/education

Funder Name

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2011		Yes	No