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

Submission date	Recruitment status	[_] Prospectively registered
05/10/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/05/2012	Urological and Genital Diseases	

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 ubiquionone 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 spermiogeram 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 x 10^6/mL ,sperm motility according to World Health Organization (WHO) 1999 criteria <50% and normal sperm morphology <30%)
3. Seminal white blood cells <1 x 10^6/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

Iran University of Medical Sciences (Iran)

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