

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

☐ Prospectively registered

☐ Protocol

Registration date

03/12/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/05/2012

Condition category

Urological and Genital Diseases

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Double-blind randomised placebo-controlled single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/10/2008

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

Age group

Adult

Sex

Male

Target number of participants

60

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)

Sponsor details

Crossing of Sheikh Fazlolah and Chamran Highway

Tehran

Iran

14155

sadeghi@avicenna.ac.ir

Sponsor type

University/education

Website

http://www.iums.ac.ir/index.php?slc_lang=en&sid=1

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Iran University of Medical Sciences (Iran)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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