Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of coenzyme Q10 on sperm functional parameters and mitochondria, and apoptotic process in infertile men

Protocol summary

Study aim
Increasing the fertility rate in men with Oligoasthenoteratozoospermia
Design
This is a single-center, open-label, randomized clinical trial with a parallel-group
Settings and conduct
This study will be conducted at Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences, Bandar Abbas.. The study population is 30 men with oligoasthenoteratospermia
Participants/Inclusion and exclusion criteria
Inclusion criteria: Infertile couple with a male cause identified by the symptoms of idiopathic oligoasthenoteratospermia. Definitive diagnosis of oligoasthenoteratospermia based on sperm count of less than 15 million per cc of semen, Sperm movement less than 32, Normal sperm morphology less than 4%. Men age range 18-50 years. Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm. Exclusion criteria: Patients with a history of reproductive system problems, including: undescended testicles, Klinefelter syndrome, hypogonadism, varicocele, cryptorchidism, azoospermia and infection in reproductive system. Patients with a history of inflammation and injury to the testicles that caused infertility. Patients with underlying disorder including: hypothalamus and pituitary diseases and with thyroid gland problems, hypervitaminosis D and A, kidney stones. History of allergy to the components of medicines: sperigen tablets and Q10 supplement
Intervention groups
Group A will be patients receiving two tablets of sperigen daily and two tablets of coenzyme Q10 100 mg (200 mg daily) for one month Group B will be patients receiving, two sperigen pills daily for one month. Group C will be patients who do not receive medication.
Main outcome variables
Sperm functional parameters; permeability of sperm mitochondrial membrane; ROS level of semen liquid; breakage rate of sperm nuclear DNA; expression of apoptosis genes: survivin and caspase 3

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220809055653N1**
Registration date: **2022-08-19, 1401/05/28**
Registration timing: **prospective**

Last update: **2022-08-19, 1401/05/28**
Update count: **0**
Registration date
2022-08-19, 1401/05/28

Registrant information
Name
Mahmoud Omidi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 76 3371 0406
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-07, 1401/07/15
Expected recruitment end date
2023-01-20, 1401/10/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of coenzyme Q10 on sperm functional parameters and mitochondria, and apoptotic process in infertile men

Public title

The effect of coenzyme Q10 on sperm in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infertile couple with a male cause identified by the symptoms of idiopathic oligoasthenoteratospermia. Definitive diagnosis of oligoasthenoteratospermia based on sperm count of less than 15 million per cc of semen, Sperm movement less than 32, Normal sperm morphology less than 4%. Men age range 18-50 years old Signing informed consent and willingness of study participant to accept randomization to any assigned treatment arm.

Exclusion criteria:

Patients with a history of reproductive system problems, including: undescended testicles, Klinefelter syndrome, hypogonadism, varicocele, cryptorchidism, and azoospermia and infection in reproductive tract and reproductive system Patients with a history of inflammation and injury to the testicles that caused infertility Patients with underlying disorder including: diabetes mellitus, hypothalamus and pituitary diseases and with thyroid gland problems, hypervitaminosis D and A, kidney stones and uncontrolled hypertension History of allergy to the components of medicines: sperigen tablets and Q10 supplement

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be performed (each block consists 6 patients). Allocation sequence and concealment codes will be generated using www.sealedenvelope.com. The closed envelope method will be used to hide the allocation sequence

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Jomhuri Eslami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2021-10-18, 1400/07/26

Ethics committee reference number

IR.HUMS.REC.1400.306

Health conditions studied

1

Description of health condition studied

Male Infertility

ICD-10 code

N46.1

ICD-10 code description

Oligospermia

Primary outcomes

1

Description

Sperm functional parameters (morphology, movement, number)

Timepoint

Before intervention and during the study and the endpoint the study

Method of measurement

Para-clinical

2

Description

Permeability of sperm mitochondrial membrane

Timepoint

Before intervention and during the study and the endpoint the study

Method of measurement

Measuring the mitochondrial membrane potential (MMP)

Secondary outcomes

1

Description
Breakage rate of sperm nuclear DNA
Timepoint
Before intervention and during the study and the endpoint the study
Method of measurement
SDFA kit

2

Description
Reactive oxygen species (ROS) level of semen liquid
Timepoint
Before intervention and during the study and the endpoint the study
Method of measurement
ROS kit

3

Description
Expression level of apoptosis genes: survivin (anti-apoptotic gene) and caspase 3 (apoptotic gene).
Timepoint
Before intervention and during the study and the endpoint the study
Method of measurement
RT-PCR

Intervention groups

1

Description
Intervention group: Oligoasthenoteratozoospermia patients receiving two tablets of sperigen daily manufactured by BioArvand Pharmed Pharmaceutical Company and two tablets of coenzyme Q10 100 mg (200 mg daily) manufactured by Golden Life Pharmaceutical Company for one month
Category
Treatment - Drugs

2

Description
Intervention group: Oligoasthenoteratozoospermia patients receiving two tablets of sperigen daily manufactured by BioArvand Pharmed Pharmaceutical company for one month.
Category
Treatment - Drugs

3

Description
Control group: Oligoasthenoteratozoospermia patients not receive medication
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Fatemeh Eini
Street address
Jomhuri Eslami Blvd
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
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research@hums.ac.ir
Web page address
http://hums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas University of Medical Sciences
Proportion provided by this source
100

Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Mahmoud Omidi
Position
Assistant professor
Latest degree
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Toxicology
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Person responsible for updating data

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Master
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mitra2276.s@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Information regarding the study outcomes will be shared.
When the data will become available and for how long
Data will become available after publication of obtained results.
To whom data/document is available
Only academic institutions
Under which criteria data/document could be used
The study protocol or proposal should be approved by Ethics committee of institutions. The rights of authors and sponsors should be respected
From where data/document is obtainable
m.omid1364@gmail.com
What processes are involved for a request to access data/document

Requests should be addressed to the Technology and Research Vice-chancellery of Hormozgan University of Medical Sciences and the project executor should informed.

Comments