

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 Omid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3371 0406

Email address

toxicology@hums.ac.ir

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

N/A

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

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Fatemeh Eini

Street address

Jomhuri Eslami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3333 0755

Fax

+98 76 3371 0393

Email

hgrc@hums.ac.ir

Web page address

<http://shmh.hums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

Emam Hossein Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3371 0393

Fax

+98 76 3371 0393

Email

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 Omid

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Toxicology

Street address

Emam Hossein Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919691982

Phone

+98 76 3371 0406

Email

m.omid1364@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Fatemeh Eini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

Street address

Jomhuri Eslami Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Phone

+98 76 3371 0393

Email

feini13@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Mitra Sahraian

Position

PharmD Student

Latest degree

Master

Other areas of specialty/work

Medical Pharmacy

Street address

Emam Hossein Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919691982

Phone

+98 76 3371 0406

Email

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