Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating effect of probiotics supplement on semen quality and expression of genes associated with oxidative stress in sperm of asthenozoospermia patients

Protocol summary

Study aim
This study aims to investigate the mechanism of probiotic medicinal effect in men with idiopathic infertility. In this regard, the effect of probiotic drug FamiLact on the expression of genes related to oxidative stress and Inflammatory pathways in addition to common sperm parameters and oxidative stress factors (MDA, H2O2 and NO) will be assessed.

Design
A phase 2-3, CoQ10 receiver-controlled group clinical trial, randomized applying permuted blocks.

Settings and conduct
52 infertile men recruited in the infertility department of Beheshti Hospital in Kashan who met the inclusion criteria, will be randomly divided into two intervention and control groups. In the current study, the laboratory researchers and statistical data analyst will be kept blind and the findings will be recorded based on the patient number. Patients will receive 500mg of probiotics and 200mg of CoQ10 medicine daily for 70 days in the intervention group and 200mg of CoQ10 medicine in the control group. Sampling and measurement of the main outcome variables of the study will be evaluated prior to intervention and after termination of the course of supplementation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: idiopathic male infertility Exclusion criteria: use of drugs affecting spermatogenesis, cytotoxic drugs, and antibiotics - varicocele and anatomical diseases - history of testicular surgery or trauma - history of chemotherapy, radiotherapy - chromosomal abnormalities, hypogonadism - recent history of UTIs - Smoking, alcohol, drugs - endocrine disorders - diabetes - BMI over 30.

Intervention groups
Treatment group: one 500 mg probiotic FamiLact capsule and two 100 mg CoQ10 capsules daily. Control group: two 100 mg CoQ10 capsules daily

Main outcome variables
Parameters of sperm quality, oxidative stress indicators in semen, expression of genes related to oxidative stress and inflammatory pathways.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230806059053N1**
Registration date: **2023-09-15, 1402/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-15, 1402/06/24**
Update count: **0**

Registration date
2023-09-15, 1402/06/24

Registrant information

Name
Tina Nazempour

Name of organization / entity

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Iran (Islamic Republic of)

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+98 31 5558 9444

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-14, 1402/06/23

Expected recruitment end date
2023-11-14, 1402/08/23

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating effect of probiotics supplement on semen quality and expression of genes associated with oxidative stress in sperm of asthenozoospermia patients

Public title
The effect of probiotic supplementation on male infertility
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of idiopathic oligoasthenospermia
Exclusion criteria:
People who take drugs affecting spermatogenesis such as tamoxifen, HCG, gonadotropin, androgens and cytotoxic drugs such as immunosuppressants, anticonvulsants, and antibiotic or antifungal drugs. People who have a diet rich in probiotics. People who have factors with a clear effect on the condition of asthenozoospermia include: varicocele, epididymovarcitis, prostatitis, history of testicular surgery, testicular trauma, testicular torsion, history of intracytoplasmic sperm injection (ICSI), history of chemotherapy, radiotherapy, abnormality. chromosomal abnormalities, cryptorchidism, hypogonadism, recent history of sexually transmitted diseases, pyospermia, smoking, alcohol, drugs, known hormonal disorders, diabetes, known liver and kidney disease, BMI over 30 Unwillingness to cooperate and participate in the study
Age
From **18 years** old to **40 years** old
Gender
Male

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by permutation blocks using random allocation software. 6 blocks of size 4 will be used to distribute samples equally between control and intervention groups. In such manner, the number of each patient is given to the software and the patient group (control or intervention) will be determined.
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 Kashan University of Medical Sciences
Street address
5th of Qotb –e Ravandi Blvd., Kashan
City
Kashan
Province
Isfehan
Postal code
8715973474
Approval date
2023-08-01, 1402/05/10
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1402.095

Health conditions studied

1

Description of health condition studied
Idiopathic oligoasthenoteratospermia
ICD-10 code
N46.9
ICD-10 code description
Male infertility, unspecified

Primary outcomes

1

Description
Gene expression
Timepoint
Before the intervention and after the intervention
Method of measurement
Real-time PCR

Secondary outcomes

1

Description
Sperm concentration
Timepoint
Before the intervention and after the intervention
Method of measurement
Semen sample analysis

2

Description
Semen volume
Timepoint
Before the intervention and after the intervention
Method of measurement
Semen sample analysis

3

Description
Percentage of abnormal sperm morphology
Timepoint
Before the intervention and after the intervention
Method of measurement
Semen sample analysis

4

Description
Percentage of sperm motility
Timepoint
Before the intervention and after the intervention
Method of measurement
Semen sample analysis

5

Description
Percentage of sperm progressive motility
Timepoint
Before the intervention and after the intervention
Method of measurement
Semen sample analysis

6

Description
Total antioxidant capacity (TAC)
Timepoint
Before the intervention and after the intervention
Method of measurement
ELISA

7

Description
Malondialdehyde (MDA) level
Timepoint
Before the intervention and after the intervention
Method of measurement
ELISA

Intervention groups

1

Description
Intervention group: The group of patients receiving 100 mg capsule of CoQ10 BD and 500 mg capsule of probiotic FamiLact daily for a period of 70 days (after food consumption). The probiotic part of this supplement consists of strains of Lactobacillus acidophilus, Lactobacillus casei, Lactobacillus rhamnosus, Lactobacillus plantarum, Bifidobacterium lactis, Bifidobacterium longum, Bifidobacterium breu, Bifidobacterium breu, Bifidobacterium breu, Bifidobacterium strum bifidocum. Also, fructo-oligosaccharide is used as a prebiotic (in fact, the food of insects) in this product.
Category
Treatment - Drugs

2

Description
Control group: The group of patients receiving 100 mg capsule of CoQ10 BD (200 mg)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Beheshti Hospital of Kashan
Full name of responsible person
Dr. Elahesadat Seyyedhoseini
Street address
Kashan, Qotb-e Ravandi Blvd, Kashan University of Medical Sciences
City
Kashan
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8715973474
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Elaheir.1987@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Elahesadat Seyyedhoseini
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City
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

2

Sponsor

Name of organization / entity

Vice Chancellor of Research & Technology

Full name of responsible person

Dr. Elahesadat Seyyedhoseini

Street address

Kashan, Qotb-e Ravandi Blvd

City

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Isfehan

Postal code

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Phone

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Email

Eelaheir.1987@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor of Research & Technology

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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Elahesadat Seyyedhoseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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Full name of responsible person

Dr. Elahesadat Seyyedhoseini

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Elahesadat Seyyedhoseini

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available