Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the Efficacy of Letrozole and L-Carnitine on Sperm Quality and Oxidative Stress in infertile Men with Idiopathic Oligoasthenoteratozoospermia: A prospective, double blind, randomized clinical trial

Protocol summary

Study aim
Comparative Evaluation of the Efficacy of Letrozole, L-Carnitine on Sperm Quality, Oxidative Stress, in infertile Men with Idiopathic Oligoasthenoteratozoospermia

Design
The clinical trial had three intervention groups in a double-blind randomized design, which used Excel software.

Settings and conduct
This study will be conducted on patients referred to Shariati Hospital. The patient, and analyst will be blinded through provided codes, a matching placebo, and information categorized in the form of letters for each group.

Participants/Inclusion and exclusion criteria
Infertile men referred to Shariati Hospital, age between 25 and 45 years, body mass index (BMI) between 18 and 25 years, normal fertility and medical history, normal findings on physical examination, sperm DNA fragmentation index (DFI) greater than 15%, and regular sexual activity with normal sexual function.

Intervention groups
Group G1: will receive letrozole (2.5 mg orally once a day), Group G2: will receive L-carnitine (1000 mg orally once a day), and Group G3: will receive a combination of both drugs at the same doses.

Main outcome variables
Improving sperm quality and ART outcomes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260502069232N1**
Registration date: **2026-06-25, 1405/04/04**
Registration timing: **retrospective**

Last update: **2026-06-25, 1405/04/04**
Update count: **0**

Registration date
2026-06-25, 1405/04/04

Registrant information
Name
davood zarini
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6405 3412
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dzarini@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-20, 1402/05/29

Expected recruitment end date
2024-06-10, 1403/03/21

Actual recruitment start date
2023-08-20, 1402/05/29

Actual recruitment end date
2024-08-01, 1403/05/11

Trial completion date
2024-11-01, 1403/08/11

Scientific title
Evaluation of the Efficacy of Letrozole and L-Carnitine on Sperm Quality and Oxidative Stress in infertile Men with Idiopathic Oligoasthenoteratozoospermia: A prospective, double blind, randomized clinical trial

Public title
effect of Letrozole, L-carnitine and their combination therapy on sperm quality and male infertility
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
body mass index (BMI) between 18 and 25 a history of normalfertility and medical background normal findings in physical examinations sperm DNAfragmentation index (DFI) greater than 15% regular sexual activity with normal sexualfunction
Exclusion criteria:
genital infections azoospermia, cryptorchidism, andvaricocele history of trauma or surgery on the testes endocrine disorders systemic diseases,and use of medications affecting fertility smoking, alcohol consumption recent antioxidanttherapy any indication of female partner infertility
Age
From **25 years** old to **45 years** old
Gender
Male

Phase
2
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
A block randomization method was used, in which screening was performed in the first stage and out of 120 patients, 30 patients were excluded from the study due to lack of inclusion or withdrawal criteria. The remaining 90 patients were randomly divided into three groups of 30 patients in blocks of six, and sealed envelopes were used to conceal allocation
Blinding (investigator's opinion)
Double blinded
Blinding description
The random sequence is generated by the software and the group code is given to the researcher. One group will take letrozole + L-carnitine placebo + combination placebo, one group will take L-carnitine + letrozole placebo + combination placebo and the third group will take letrozole + L-carnitine + closed design (without additional placebo). All patients take the same number of tablets/capsules daily. For the analyst; the data for each group is provided to him in the form of a, b and c.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee, Faculty of Medicine, Tehran University of Medical Sciences
Street address
Qods street, Enghelab Square, Tehran Town
City
Tehran
Province
Tehran
Postal code
1461884513
Approval date
2024-12-21, 1403/10/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1403.465

Health conditions studied

1

Description of health condition studied
Male infertility remains a major challenge in reproductive medicine, withidiopathic oligoasthenoteratozoospermia accounting for a substantial proportion of cases
ICD-10 code
Z31.41
ICD-10 code description
Encounter for fertility testing

Primary outcomes

1

Description
progressive motility of sperm
Timepoint
Before performing the ART technique
Method of measurement
using a phase contrast microscope (Olympus LX71, Japan) at a magnification of400×

2

Description
sperm concentration
Timepoint
Before performing the ART technique
Method of measurement
using a phase contrast microscope (Olympus LX71, Japan) at a magnification of400×

3

Description
sperm morphology
Timepoint
Before performing the ART technique
Method of measurement
using a phase contrast microscope (Olympus LX71, Japan) at a magnification of400×

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group one: Received letrozole tablets. Name of the substance used: Letrozole - Chemical composition and concentration: 2.5 mg tablet containing the active ingredient letrozole ($C_{17}H_{11}N_5$) - Manufacturer: Soha Pharma Co., Iran - Dosage: 2.5 mg (one whole tablet) once a day - Duration of treatment: 3 consecutive months (90 days) - Method of administration: Orally and after dinner (in order to reduce possible gastrointestinal side effects and increase patient adherence to treatment). Additional notes on interventions:1. Adherence to treatment: In order to increase patient adherence to the treatment regimen, patients are asked to complete a daily medication record sheet and at the end of each month, the number of pills is counted. 2. Complication management: A regular monthly follow-up program is planned by an andrology specialist to assess possible complications (such as decreased libido, fatigue, mood swings, and arthralgia) and to perform periodic hormonal tests. 3. Equipment and measurement methods: All assessments will be performed using standard and up-to-date equipment and in strict compliance with WHO guidelines (2021 version).
Category
Rehabilitation

2

Description
Second intervention group (L-carnitine treatment):- Name of the active ingredient: L-carnitine - Chemical composition and concentration: 1000 mg capsule containing the active ingredient L-carnitine - Manufacturer: Karen Pharma Co., Iran - Dosage: 1000 mg (one whole capsule) once a day - Duration of treatment: 3 consecutive months (90 days) - Method of administration: Orally after dinner. Additional notes on interventions:1. Adherence to treatment: In order to increase patient adherence to the treatment regimen, patients are asked to complete a daily medication record sheet and at the end of each month, the number of pills is counted. 2. Complication management: A regular monthly follow-up program is planned by an andrology specialist to assess possible complications (such as decreased libido, fatigue, mood swings, and arthralgia) and to perform periodic hormonal tests. 3. Equipment and measurement methods: All assessments will be performed using standard and up-to-date equipment and in strict compliance with WHO guidelines (2021 version).
Category
Rehabilitation

3

Description
Third intervention group (combination therapy) - Name of the substance used: Letrozole + L-carnitine - Chemical composition and concentration: 2.5 mg Letrozole tablet + 1000 mg L-carnitine capsule - Manufacturer: Soha Pharma Co. and Karen Pharma Co., Iran - Dosage: 2.5 mg Letrozole + 1000 mg L-carnitine (one tablet + one capsule) once a day - Duration of treatment: 3 consecutive months (90 days) - Method of administration: Orally, after dinner. Additional notes on interventions:1. Adherence to treatment: In order to increase patient adherence to the treatment regimen, patients are asked to complete a daily medication record sheet and at the end of each month, the number of pills is counted. 2. Complication management: A regular monthly follow-up program is planned by an andrology specialist to assess possible complications (such as decreased libido, fatigue, mood swings, and arthralgia) and to perform periodic hormonal tests. 3. Equipment and measurement methods: All assessments will be performed using standard and up-to-date equipment and in strict compliance with WHO guidelines (2021 version).
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Infertility Clinic of Shariati Hospital,
Full name of responsible person
Fardin Amidi
Street address
North Kargar Street, Jalal Al-Ahmad Intersection, Shariati Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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1417653761
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Azim Hedayatpour
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Anatomy
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Yes - There is 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

Title and more details about the data/document

Data analysis will be published in the form of an article.

When the data will become available and for how long

After the article is accepted

To whom data/document is available

All researchers

Under which criteria data/document could be used

In order to expand the study and pave the way for further studies

From where data/document is obtainable

Faculty of Medicine; Department of Anatomy

What processes are involved for a request to access data/document

In-person visit; or email

Comments