

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Email address

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 normal fertility and medical background normal findings in physical examinations sperm DNA fragmentation index (DFI) greater than 15% regular sexual activity with normal sexual function

Exclusion criteria:

genital infections azoospermia, cryptorchidism, and varicocele history of trauma or surgery on the testes endocrine disorders systemic diseases, and use of medications affecting fertility smoking, alcohol consumption recent antioxidant therapy 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, with idiopathic 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 of 400x

2**Description**

sperm concentration

Timepoint

Before performing the ART technique

Method of measurement

using a phase contrast microscope (Olympus LX71, Japan) at a magnification of 400x

3

Description

sperm morphology

Timepoint

Before performing the ART technique

Method of measurement

using a phase contrast microscope (Olympus LX71, Japan) at a magnification of 400x

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 (C₁₇H₁₁N₅) - 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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nima Rezaei

Street address

Qods street, Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6405 3412

Email

tumsmc@tums.ac.ir

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

Street address

Poursina Street; Faculty of Medicine; Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6405 3412

Email

hedayatpour@sina.tums.ac.ir

Person responsible for scientific 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

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Postal code

1417653761

Phone

+98 21 6405 3412

Email

hedayatpour@sina.tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Davood Zarini

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Anatomy

Street address

Poursina Street; Faculty of Medicine; Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 6405 3412

Email

dzarini@sina.tums.ac.ir

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