

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effects of antioxidant with high dose L-carnitine on count, morphology and motility in infertile patients semen analysis

Protocol summary

Study aim

Determine the efficacy of supplement with L-carnitine on semen parameters

Design

To implement this project, all patients with male infertility referred to Infertility Clinic of Ayatollah Taleghani Hospital have been investigated and Based on inclusion and exclusion criteria were selected and matched for age and BMI.

Settings and conduct

To implement this project, all patients with male infertility referred to Infertility Clinic of Ayatollah Taleghani Hospital have been investigated and Based on inclusion and exclusion criteria were selected and matched for age and BMI. After entering the plan, the semen analysis is first taken from the reference laboratory. For 3 months, Androferti is prescribed as a drug that is higher than the L-carnitine dose than the usual antioxidants. After three months, patients are called by infertility colleagues and sperm analysis is performed again and the results are compared with the initial test.

Participants/Inclusion and exclusion criteria

Infertile men between 20-45 years old with idiopathic oligoasthenoteratospermia, BMI less than 30, No smoking and drug, Lack of azoospermia Unwillingness to participate in the design or continuation of the treatment process, Drug intolerance

Intervention groups

Total infertile men with idiopathic oligoasthenospermia treated by L-carnitine supplement twice orally daily

Main outcome variables

Changing the count, motility and normal morphology in semen analysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190426043379N1**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

Registration date

2019-06-16, 1398/03/26

Registrant information

Name

Ferdoos Jahanmardi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6604 9733

Email address

f.jahanmardi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-31, 1398/03/10

Expected recruitment end date

2020-05-30, 1399/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of antioxidant with high dose L-carnitine on count, morphology and motility in infertile patients semen analysis

Public title

Effects of high dose L-carnitine on semen parameter in infertile patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age less than 45 years BMI less than 30 No smoking and drug Lack of azoospermia Sperm count is less than 15 million Sperm motility less than 32% Normal morphology less than 4%

Exclusion criteria:

Unwillingness to participate in the design or continuation of the treatment process Drug intolerance

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of medical Sciences

Street address

Arabi Ave, Velenjak

City

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Province

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Postal code

1985717443

Approval date

2019-03-17, 1397/12/26

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1359

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N46

ICD-10 code description

Male infertility

Primary outcomes

1

Description

Sperm count less than 15 million

Timepoint

Beginning of the project and after three months

Method of measurement

Laboratory

2

Description

Sperm motility less than 32%

Timepoint

Beginning of the project and after three months

Method of measurement

Laboratory

3

Description

Normal morphology less than 4%

Timepoint

Beginning of the project and after three months

Method of measurement

Laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients with male factor infertility receive Androferti as a drug with high dose L-Carnitine for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

Ferdoos Jahanmardi

Street address

Arabi street, Velenjak, Tehan

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1985711151

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Prevention of gynecological Research Center (66000104)

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Salehpour Saghar

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Salehpour Saghar

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Methodology, statistical analysis

When the data will become available and for how long

Starting available 6 months after the publication of results

To whom data/document is available

Researchers working in academic and scientific institutions and individuals who are working in industry

Under which criteria data/document could be used

For similar research, new research collaboration

From where data/document is obtainable

Corresponding Author Email Address

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

Applicant is evaluated up to 2 months

Comments