Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
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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 Univercity of medical Sciences
Street address
Arabi Ave, Velenjak
City
Tehran
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Zarghi Afshin
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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
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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