

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of combination use of pentoxifylline and L-carnitine on Idiopathic Oligoasthenoteratozoospermia

Protocol summary

Summary

The main objective of this double-blind prospective clinical study is to evaluate the combined effects of pentoxifylline (PX) and L-carnitine in improving the quality of sperm parameters in infertile men with idiopathic (iOATS) oligoasthenoteratozoospermia and help to enhance Assisted reproductive technique (ART) rankings choice. The main inclusion criteria was infertile men with iOATS and also main exclusion criteria was infertile men with known OATS, 255 infertile men with iOATS allocated in a double-blind, placebo-controlled randomized clinical trial (DBRCT) and finally 212 men finished the study. They randomized to four groups. Group one received 400 mg PX/ and 400 mg L-carnitine twice daily, group two 400 mg PX/ and placebo twice daily, group three 400 mg L-carnitine with placebo twice daily and group four received PX placebo with L-carnitine placebo tablets twice daily for 3 months. From patients of all groups two semen samples (one before and one after intervention) were evaluated. Semen parameters of sperm concentration, total and fast progressive motility (%) and morphology (%) were analyzed for each sample and also according to quality of sperm parameters they categorized for ART procedures rates

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310131981N3**

Registration date: **2014-07-21, 1393/04/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-21, 1393/04/30

Registrant information

Name

Ali Asghar Ketabchi

Name of organization / entity

Kerman University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research deputy of Kerman University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combination use of pentoxifylline and L-carnitine on Idiopathic Oligoasthenoteratozoospermia

Public title

The effect of combination use of pentoxifylline and L-carnitine on sperm-analysis of Idiopathic Oligoasthenoteratozoospermia patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :infertile men with Oligoasthenoteratozoospermia; men with age between 25- 40 years old; men without history of medical or

surgery for infertility ;men with wives with ages between 20 - 35 years old and or with no known female fertility risk factors . Exclusion criteria:infertile men with Oligoasthenoteratozoospermia with known etiologies.

Age

From **25 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **212**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Center of Kerman Medical Sciences
University

Street address

kerman Medical Sciences University

City

kerman

Postal code

Approval date

2008-06-21, 1387/04/01

Ethics committee reference number

285/ 91

Health conditions studied

1

Description of health condition studied

male infertility

ICD-10 code

N46

ICD-10 code description

male infertility

Primary outcomes

1

Description

spermogram parameters change

Timepoint

after intervention

Method of measurement

spermogram

2

Description

Assisted reproductive technic rates

Timepoint

before intervention

Method of measurement

spermogram

Secondary outcomes

1

Description

spermogram improving

Timepoint

after 3 months from intervention

Method of measurement

spermogram

2

Description

qualification of Assisted reproductive technic rates

Timepoint

3 months after intervention

Method of measurement

spermogram

Intervention groups

1

Description

The intervention group one consumed orally 400 mg pentoxifylline and 400 mg L-carnitin twice daily for 3 months

Category

Treatment - Drugs

2

Description

The intervention group two consumed orally 400mg pentoxifylline and placebo twice daily for 3 months

Category

Treatment - Drugs

3

Description

The intervention group three consumed orally 400mg L-carnitin and placebo twice daily for 3 months

Category

Treatment - Drugs

4

Description

The control group fourth consumed orally two type placebos twice daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility center of Afzalipour Hospital

Full name of responsible person

Dr.Ali Asghar Ketabchi

Street address

Afzalipour Hospital

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Medical Sciences University of kerman

Full name of responsible person

Dr. Hamid Najafi

Street address

Research Center of kerman Medical Sciences University

City

kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Medical Sciences University of kerman

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Research Center of kerman Medical Sciences University

Full name of responsible person

Dr.Gholamreza Sepehri

Position

Pharmacologist and Director of Kerman Medical Sciences University research center

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Center of kerman Medical Sciences University

Full name of responsible person

Ali Asghar Ketabchi

Position

Urologist ,Associate professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

professor of pharmacology ,Director of Research Center of kerman Medical sciences university

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty