

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Alpha lipoic acid supplementation on gene expression and activity of Glutathione S-Transferase and spermatogram in idiopathic asthenozoospermic males: A randomized, triple-blind, placebo-controlled clinical trial

Protocol summary

Summary

The present study was designed to determine the effects of Alpha-lipoic acid supplementation on semen quality, seminal antioxidant enzymes, oxidative stress and the gene expression and activity of Glutathione S-Transferase of sperm in idiopathic oligoasthenoteratozoospermic men referring to treatment center Ahvaz University of Medical Sciences. In a randomized placebo-controlled trial, 40 infertile men aged between 20-45 years with idiopathic oligoasthenoteratozoospermia and at least 1 year history of infertility selected. The enrolled patients underwent dietary implementation of Alpha-lipoic acid 600 mg twice daily (300mg) or placebo For 12 weeks. During this study, the total antioxidant capacity (TAC) and serum malondialdehyde (MDA) and the gene expression and activity of Glutathione S-Transferase of sperm are evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111010181N3**

Registration date: **2013-11-15, 1392/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-15, 1392/08/24

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Ahvaz Jundishapur University of Medical Science

Expected recruitment start date

2013-11-16, 1392/08/25

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Alpha lipoic acid supplementation on gene expression and activity of Glutathione S-Transferase and spermatogram in idiopathic asthenozoospermic males: A randomized, triple-blind, placebo-controlled clinical trial

Public title

The effect of Alpha lipoic acid supplementation on male infertility

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willing to participate in the study and

filling out the informed consent form; they should be infertile (no conception after 12 months intercourse without any contraception); age 20-45 y.o; idiopathic asthenospermia according to WHO criteria; normal hormonal profile. Exclusion criteria: any infection in genitourinary (GU) tract; any anatomical abnormality in GU tract; any chronic disease during last 3 months; any surgery in GU tract; consumption of antioxidant supplements during last 3 months.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Science

Street address

Golestan Ave. Ahvaz Jundishapur University of Medical Science

City

Ahvaz

Postal code

Approval date

2013-10-12, 1392/07/20

Ethics committee reference number

150

Health conditions studied

1

Description of health condition studied

Asthenospermia

ICD-10 code

N46

ICD-10 code description

male infertility

Primary outcomes

1

Description

sperm motility

Timepoint

12 weeks

Method of measurement

spermatogram

Secondary outcomes

1

Description

gene expression and activity of Glutathione S-Transferase

Timepoint

12 weeks

Method of measurement

Real Time-PCR- Spectrophotometric

Intervention groups

1

Description

Control group:Placebo placebo: Lactose, 12 weeks, 2 capsule(300 mg) per day

Category

Treatment - Drugs

2

Description

Intervention group:Alfa lipoic acid 600 mg per day for12 weeks, 2 capsule per day(300mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Infertility Center of Imam Khomeini Hospital, Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Heidari

Street address

Infertility Center of Imam Khomeini Hospital, Ahvaz University of Medical Sciences.Ahvaz

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Dr. Fegghi

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Ahvaz Jundishapur University of Medical Science,
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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

Ahvaz Jundishapur University of Medical Science

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**

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Full name of responsible person

Dr. Fatemeh Heidari

Position

Associate Professor

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Web page address

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