

# 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)

##### Phone

+98 61 1373 8255

##### Email address

haidari-f@ajums.ac.ir

##### 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

Ahvaz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Science

**Full name of responsible person**

Dr. Fegghi

**Street address**

Ahvaz Jundishapur University of Medical Science,  
Golestan Ave.

**City**

Ahvaz

**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**

Ahvaz Jundishapur University of Medical Science

**Full name of responsible person**

Dr. Fatemeh Heidari

**Position**

Associate Professor

**Other areas of specialty/work****Street address**

Golestan Ave. Dept. of Nutrition, School of  
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Science

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*