

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Omega-3 fatty acids plus vitamin E supplements on spermatogram and oxidative stress in infertile men with asthenozoospermia

Protocol summary

Summary

It is believed that environmental and nutritional factors are involved in infertility of men. Recent studies have shown that omega-3 fatty acids especially DHA is reduced in cell membrane of sperm in those with asthenozoospermia. The authors have treated these patients with DHA (Docosahexaenoic Acid) supplementation, but they could not find any progress. We think that if vitamin E plus DHA will be given to these patients, we will see the improvement in the motility of the sperm. In this study, we are going to see the effect of Omega-3 plus vitamin E on sperm motility in a double blind placebo controlled randomized clinical trial. The cases will be treated with 1000mg DHA plus 600mg vitamin E, and controls will be treated with placebo and 600 mg vitamin E. After 3 months, the spermatogram and oxidative stress will be compared before and after treatment in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010054010N3**
Registration date: **2010-10-28, 1389/08/06**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-10-28, 1389/08/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

National nutrition research institute

Expected recruitment start date

2010-11-13, 1389/08/22

Expected recruitment end date

2012-03-12, 1390/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Omega-3 fatty acids plus vitamin E supplements on spermatogram and oxidative stress in infertile men with asthenozoospermia

Public title

The effect of Omega-3 fatty acids plus vitamin E supplements on spermatogram and oxidative stress in infertile men with asthenozoospermia

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 omega-3 fatty acids and/or vitamin E supplements during last 3 months .

Age

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

Gender

Male

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **50**

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**

Avicenna Research Institute

Street address

Shahid Beheshti University

City

Tehran

Postal code**Approval date**

2009-10-12, 1388/07/20

Ethics committee reference number

57

Health conditions studied**1****Description of health condition studied**

Asthenospermia

ICD-10 code

N045

ICD-10 code description

male infertility

Primary outcomes**1****Description**

sperm motility

Timepoint

3 months

Method of measurement

spermatogram

Secondary outcomes**1****Description**

oxidative stress

Timepoint

3 months

Method of measurement

total antioxidant capacity and PGF2a

Intervention groups**1****Description**

Control group: placebo 1g per day for 3 months + 600mg vitamin E

Category

Treatment - Drugs

2**Description**

Intervention group: omega-3 fatty acids 1000mg per day for 3 months + 600mg vitamin E

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Avicenna clinic

Full name of responsible person

Azita Hekmatdoost

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Niavaran Ave

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

National Nutrition Research Institute

Full name of responsible person

Dr. Abdollahi

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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

National Nutrition Research Institute

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

National Nutrition Research Institute

Full name of responsible person

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Person responsible for updating data**Contact****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*