

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of omega-3 supplementation on semen profile (semen volume, sperm count, sperm motility, sperm morphology) in infertile men

Protocol summary

Study aim

Investigating the effect of omega-3 supplement treatment on the spermogram disorder of infertile men, including the recovery rate of seminal fluid volume, sperm count, sperm motility rate, and sperm shape.

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 58 patients. Randomized permutation block method was used for randomization.

Settings and conduct

After fully explaining the research plan and obtaining informed consent, infertile men with spermogram disorders referring to the treatment clinics of Ghaem Hospital in Mashhad are included in the study. After examining the exclusion criteria, the patients are divided into two groups. In the control group, in addition to the necessary and routine treatments, a placebo is used daily for 3 months. In the intervention group, in addition to the routine treatment, oral omega-3 treatment with a dose of 1000 mg per day is performed for 3 months. Three months after the start of the study, new spermograms will be performed in both groups and will be compared and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile men aged 20-45 years not taking Omega 3 supplements in the last 6 months
Exclusion criteria: The presence of underlying disease disrupting spermogram Smoking and alcohol consumption Occupations related to high temperatures

Intervention groups

In the control group, in addition to the necessary and routine treatments to improve the spermogram disorder, a placebo is used daily for 3 months. In the intervention group, in addition to the routine treatment, oral omega-3 treatment with a dose of 1000 mg per day is performed for 3 months.

Main outcome variables

The volume of seminal fluid, the number and concentration of sperm, the amount of sperm movement

and the amount of normal morphology of sperm at the beginning and 3 months after consuming omega-3.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230403057812N1**

Registration date: **2023-06-10, 1402/03/20**

Registration timing: **prospective**

Last update: **2023-06-10, 1402/03/20**

Update count: **0**

Registration date

2023-06-10, 1402/03/20

Registrant information

Name

Niki Taziki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3255 6218

Email address

tazikin951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of omega-3 supplementation on semen profile (semen volume, sperm count, sperm motility, sperm morphology) in infertile men

Public title

Omega-3 supplementation in infertile men

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile men aged 20-45 years with abnormal spermogram Not taking omega 3 supplements in the last 6 months

Exclusion criteria:

Presence of known underlying disease for spermogram disorder Smoking and alcohol consumption Having jobs where there is a possibility of damage to sperm DNA due to high temperature

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be determined by random block method with blocks of 4 and using random numbers table of Random Allocation Software. Blocking and allocation sequence for concealment will be done by a person not involved in the research. Allocation ratio of samples will be 1:1 and they will be placed in two groups. Then, based on the obtained blocks and according to the allocation sequence, the drugs will be given to the patients. The method is that we determine the number of blocks according to the sample size. Each block is numbered and is used for 4 patients. For example, if block number 2 is selected and its treatment group is ABAB, the first patient will receive treatment A, the second patient will receive treatment B, the third patient will receive treatment A, and the fourth patient will receive treatment B.

Blinding (investigator's opinion)

Single blinded

Blinding description

After obtaining consent, the patients are included in the study and then they are divided into two control and intervention groups. Because the patients of the control group receive placebo, the intervention and control groups will not be distinguishable. Medicine and placebo are completely similar to each other in terms of shape, color and route of administration.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Faculty of Medicine, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.162

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

male infertility

ICD-10 code

N46.1

ICD-10 code description

Oligospermia

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

Spermogram disorders (semen fluid volume, sperm count, sperm movement rate, sperm shape)

Timepoint

At the beginning of the study, the spermogram sample is examined, and then after three months of daily consumption of omega-3 tablets, the spermogram sample is examined again.

Method of measurement

Sperm sample analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group, in addition to routine treatment, oral omega-3 treatment with a dose of 1000 mg per day is performed for 3 months. According to the time period of spermatogenesis (about 74 days) and previous studies, the treatment time with Omega 3 supplement was three months and its dose was considered to be 1000 mg daily. Due to the different dose of docosahexaenoic acid (DHA) in omega 3 thousand mg supplements available in Iran, for all patients, an omega 3 supplement containing the same amount of DHA (about 465 mg) is used. In this study, the capsule made by Karen company is used.

Category

Treatment - Drugs

2

Description

Control group: in the control group, in addition to the necessary and routine treatments to improve the spermogram disorder, a placebo is used daily for three months. Placebo capsule is prepared from Tasnim company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Bagher Soleimani

Street address

Ahmedabad St., Ghaem Hospital

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9919991766

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayor Mobarhan

Street address

Ghoreshi Building, next to Hoyze cinema, University St.

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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

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Niki Taziki

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific

inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available