Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Impact of Omega-3 Fatty Acids Supplements on Dry Eye

Protocol summary

Summary

Dry eye is a common medical condition in Tehran due to air pollution and dry climate. Other than the lid hygiene and artificial tears drop which replaces the evaporated tears there is definite treatment for this condition. Previous clinical experience has shown that Omega-3 supplements can improve dry eye condition. This clinical trial is designed to observe the impact of Omega-3 Supplements on clinical signs and symptoms of dry eye. The subjects are divided into two groups of treatment and control. The treatment group would receive 1 gram of Omega-3 Capsule b.i.d. The control group would receive 1 gram of Placebo Capsule b.i.d. for 1 month. Before and After treatment, the OSDI questionnaire would be completed, Tear Break Up time and Schirmer test Without anesthetic would be performed. The Omega-3 Supplements and placebo capsules are manufactured by Zahravi Pharmaceutical Company, Iran.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012265467N1**
Registration date: **2012-04-03, 1391/01/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-03, 1391/01/15

Registrant information

Name
Haleh Kangari
Name of organization / entity
College of Rehabilitation, Shahid Beheshti University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Impact of Omega-3 Fatty Acids Supplements on Dry Eye

Public title

The Impact of Omega-3 on Dry Eye

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Subjects with Tear Break up time of less than 10 seconds Exclusion Criteria: The subjects with blood coagulation problems and those who take blood thinning medications such as warfarin or Coumadin, subject with the history of stomach ulcer, hemorrhage, or surgery in the past three months, history of allergies to fish oil or gelatinous capsules.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

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

Ŝhahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yeman Ave., Chamran Highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2011-09-11, 1390/06/20

Ethics committee reference number

6066-7245-93-01-89

Health conditions studied

1

Description of health condition studied

Dry eye

ICD-10 code

H04.1

ICD-10 code description

other disorders of lacrimal gland

Primary outcomes

1

Description

Tear Break Up time

Timepoint

Before and after one month intervention

Method of measurement

The time that takes for the first dry spot to appear following blinking after fluorescin instillation

2

Description

Tear secretion

Timepoint

Before and after intervention

Method of measurement

Schirmer test- Wetting of the filter paper after 5 minutes

3

Description

Foreign body sensation, photophobia, blur vision, Burning

Timepoint

Before and after intervention

Method of measurement

Filling OSDI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Omega-3 Capsule b.i.d. for one month

Category

Treatment - Drugs

2

Description

Placebo gelatinous capsule b.i.d for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences, Faculty of Rehabilitation

Full name of responsible person

Dr. Haleh Kangari

Street address

College of Rehabilitation, Next to Bakhshifard Street, Damavand Ave., Emam Hossein Square, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Dr. Mohammad Hossein Eftekhari 's Private Practice

Full name of responsible person

Azam Sardari

Street address

İNo. 1955 Shariati Ave. ,Close to Ghods Square, Tehran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mehri Ghassemi, College of Rehabilitation, Shahid Beheshti University of Medical Sciences

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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

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences, Faculty of Rehabilitation, Optometry Department

Full name of responsible person

Dr. Haleh Kangari

Position

Doctor of Optometry, Head of Optometry Department

Other areas of specialty/work

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Person responsible for updating data

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MS student

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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