Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial comparing the effects of omega-3 supplements and artificial tear drops on dry eye symptoms after surgery, cataract emulsification methods

Protocol summary

Summary

This study is a clinical trial and be carried on in Farabi Ophthalmology Center that examine the dry-eye symptoms following a Phacoemulsification Cataract Surgery. The volunteers fill the Ocular Surface Disease questionnaire, and they are selected if : (1)Dry-eye symptoms following Phacoemulsification Cataract Surgery (2) The questionnaire index is equal or more than 30. (3) The Schirmer test is 10 millimeter or less.This is done by putting the spesific tape on the bottom corner of the eye and measured in millimeter. (4) The Tear Break up Times is 7 seconds or less.This is the time between the last blink and the first sign of Fluorescein change on the ocular surface, and can be seen with the slit lamp. (5) Lack of eye trauma (6) The absence of uveitis The patients are excluded if they have historic eye surgeries,those who are using contact lenses and suffering from systemic diseases such as Sjogren, Diabetic Retinopathy that cause dry eye . We will record all the relevant information from the abberometry and acuity vision examinations. In this study we investigate 60 eyes. The selected volunteers are randomly divided in two groups,(A) trial and (B) control, by someone who is unaware of tests results. The control group takes a drop of Artificial Tear every 6 hours a day for three months and the trial group takes Artificial Tear in the same way as control group as well as Omega-3 capsules three times a day for three months . After three months, we repeat all the above-mentioned tests including acuity vision and Abberometry Examination , Schirmer and Tear breakup time tests. The patients will also answer the Ocular Surface Disease Index Questionnaire . We will then compare the results of these two groups . The main outcome of this study is to compare the effects of omega-3 supplements and artificial tear drops on dry eye symptoms after surgery, cataract emulsification method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062413567N4**
Registration date: **2013-11-01, 1392/08/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-11-01, 1392/08/10

Registrant information

Name

Mehrdad Mohammadpour

Name of organization / entity

Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Farabi Ophthalmology Research Center

Expected recruitment start date

2013-08-07, 1392/05/16

Expected recruitment end date

2013-11-07, 1392/08/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial comparing the effects of omega-3 supplements and artificial tear drops on dry eye symptoms after surgery, cataract emulsification methods

Public title
Impact of Omega-3 supplement on dry eye treatment
Purpose
Treatment
Inclusion/Exclusion criteria
The Inclusion criteria: 1-Dry-eye symptoms following Phacoemulsification Cataract Surgery 2-Index of 30 or more from the Ocular Surface Disease Questionnaire 3-The Schirmer test of 10 millimeter or less 4-The Tear Break up Times of 7 seconds or less 5-Lack of eye trauma 6-The absence of uveitis Exclusion criteria: 1-Surgery on eyes including Surgical Correction of Refractive Errors 2-Using contact lenses 3-Systemic diseases which cause dry eye such as Sjogren ,Diabetic Retinopathy and end organ damage disease
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Central Organization of University, Qods Ave.,Keshavarz Blvd.,Vali-e-Asr Square,Tehran,Iran.
City
Tehran
Postal code

Approval date
2013-07-14, 1392/04/23
Ethics committee reference number
130/672/92/د

Health conditions studied

1

Description of health condition studied
Dry eye syndrome
ICD-10 code
H04.1
ICD-10 code description
Other disorders of lacrimal gland

Primary outcomes

1

Description
Eye problems in performing daily
Timepoint
Before intervention-Three months after treatment
Method of measurement
Ocular Surface Disease Index Questionnaire

2

Description
Tear break up time
Timepoint
Before intervention-Three months after treatment
Method of measurement
Measured in seconds -With timer and Slit Lamp

3

Description
Moisture eye
Timepoint
Before intervention-Three months after treatment
Method of measurement
Schirmer Test -Millimeters

4

Description
Visual acuity
Timepoint
Before intervention-Three months after treatment
Method of measurement
Snelen chart

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : The first patient with a unique code (1) be given package A (i.e. oral Omega-3 capsules plus Artelac Eye Drops) . Patients need to instil a drop of artificial Eye Drops , with trademark of Artelac , every 6 hours a day for three months. It contains 1.6 milligram (0.5 millilitre) of artificial tears mainly hypromellose. In addition participants in the intervention group should take 1000 mg oral Omega-3 capsules three times a day after meal (morning, noon and evening)for three months. One Omega-3 capsule, with trademark of Vita Natural Fish Oil Capsules, contains 180 milligram Eicosapentaenoic Acid and 120 milligram of Docosahexaenoic Acid. Volunteers continue this treatment for three months and return for examination afterwards.

Category

Treatment - Drugs

2

Description

Control group: The second patient with a unique code (2) be given package B (i.e. Artelac Eye Drops). Patients in the control group need to instil a drop of artificial Eye Drops, with trademark of Artelac from Bausch and Lomb Germany, every 6 hours a day for three months . It contains 1.6 milligram (0.5 millilitre) of artificial tears mainly hypromellose. Volunteers continue this treatment for three months and return for examination afterwards.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Center

Full name of responsible person

Mehrdad Mohammadpour

Street address

Excimer Clinic,Farabi Hospital,Ghazvin square,South Kargr Avenue,Enghelab Square,Tehran,Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Science

Full name of responsible person

Doctor Akbar Fotouhi

Street address

Seventh floor,Central Organization Building,Qods Ave.,Keshavarz Blvd.,Vali-e-Asr Square,Tehran,Iran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mehrdad Mohammadpour

Position

Associate Professor of Tehran University of Medical Science

Other areas of specialty/work

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Person responsible for scientific inquiries

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Anterior Segment and Cornea Fellowship

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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