

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of oral omega-3 supplementation on intraocular pressure in normotensive adults referring to ophthalmology clinics of Golestan University of Medical Sciences

Protocol summary

Study aim

Determining the effect of omega-3 oral supplements on intraocular pressure(IOP) in patients referred to the ophthalmology clinic of 5th Azar Hospital

Design

Pre-test and post-test clinical trial, phase 3 on 47 patients

Settings and conduct

All patients referred to the ophthalmology clinic of 5 Azart Hospital will be visited by an ophthalmologist and the condition of the optic nerve head and the anterior chamber angle will be examined with a slit lamp and the intraocular pressure will be measured by a Goldman applanation tonometer. Patients who do not have a diagnosis of glaucoma on examination and the anterior chamber angle is open with both eyes and have a normal intraocular pressure (less than 21) are included in the study. At the time of referral, complete demographic characteristics and blood pressure, waist circumference, height, measured weight and values of Fasting blood sugar, triglycerides and HDL are recorded.

Participants/Inclusion and exclusion criteria

Outpatients referred to 5 Azar Medical Center who are over 18 years old, have no history of intraocular surgery, have normal intraocular pressure (less than 21), are candidates for study. People taking a drug that affects lipid profile or have a previous diagnosis of glaucoma are excluded from the study

Intervention groups

All patients will be prescribed an omega-3 supplement containing 1000 mg of omega-3 for 90 days.

Main outcome variables

Intraocular pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201011048989N1**

Registration date: **2020-11-14, 1399/08/24**

Registration timing: **retrospective**

Last update: **2020-11-14, 1399/08/24**

Update count: **0**

Registration date

2020-11-14, 1399/08/24

Registrant information

Name

Marjan Akbari Kamrani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3116 3354

Email address

dr.kamrani@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2020-11-10, 1399/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral omega-3 supplementation on intraocular

pressure in normotensive adults referring to ophthalmology clinics of Golestan University of Medical Sciences

Public title

Evaluation of omega-3 oral supplementation effect on intraocular pressure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 years and older Satisfaction to participate in the study No contraindications to the use of omega-3 supplements in patients Do not take drugs that affect the lipid profile in the study Normal intraocular pressure (less than 21)

Exclusion criteria:

Lack of follow-up of patients during the study period Not interested in participating in the study History of intraocular surgery The need for intraocular surgery, including glaucoma surgery during the study period People who have to stop or not continue omega 3 due to the need for surgery People who have been prescribed more therapeutic doses of omega-3s due to a nutritional illness People who have taken omega-3 supplements before studying Taking drugs that affect lipid profile during the study Intraocular pressure above 21 Previous diagnosis of glaucoma Having angle-closure glaucoma

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **47**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical

Sciences

Street address

Gorgan, at the beginning of Shast Kola Road

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2020-10-11, 1399/07/20

Ethics committee reference number

IR.GOUMS.REC.1399.223

Health conditions studied

1

Description of health condition studied

Intraocular pressure

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Measurement of intraocular pressure at the beginning of the study and 90 days after starting omega 3 supplementation

Method of measurement

Goldmann applanation tonometry

Secondary outcomes

1

Description

Body mass index

Timepoint

At beginning of the study

Method of measurement

Weight in kilograms divided by height squared in meters

2

Description

Blood pressure

Timepoint

At the beginning of the study

Method of measurement

Hand barometer

3

Description

Fasting blood sugar

Timepoint

At the beginning of the study

Method of measurement

Blood test

4

Description

Triglyceride

Timepoint

At the beginning of the study

Method of measurement

Blood test

5

Description

High-density lipoprotein cholesterol

Timepoint

At the beginning of the study

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: For all patients, omega-3 supplements will be prescribed daily for one omega-3 oral capsule of Minoo Pharmaceutical Company containing 1000 mg of omega-3 and 180 mg of echopentanoic acid and 120 mg of docosahexaenoic acid in the form of SOFT GELL. All patients are advised not to change their diet during the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ophthalmology Clinic of 5 Azar Hospital, Gorgan

Full name of responsible person

Marjan Kamrani

Street address

5 Azar Hospital, 5 Azar St., Gorgan,

City

Gorgan

Province

Golestan

Postal code

4917761551

Phone

+98 17 3222 0561

Fax

+98 17 3223 8363

Email

gsm@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Rza Honarvar

Street address

Golestan University of Medical Sciences, At the beginning of Shast Kola Road, Gorgan,

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 0021

Email

gsm@goums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Marjan Akbari Kamrani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

Street address

5th Azar Hospital, 5th Azar Blv., Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

4917761551

Phone
+98 17 3116 3354
Fax
Email
dr.kamrani@goums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Marjan Akbari Kamrani
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
5th Azar Hospital, 5th Azar Blv., Gorgan, Iran
City
Gorgan
Province
Golestan
Postal code
4917761551
Phone
+98 17 3116 3354
Fax
Email
dr.kamrani@goums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Marjan Akbari Kamrani
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Ophthalmology
Street address
5th Azar Hospital, 5th Azar Blv., Gorgan, Iran
City
Gorgan
Province

Golestan
Postal code
4917761551
Phone
+98 17 3116 3354
Fax
Email
dr.kamrani@goums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared after people are not identified

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Study data or documentation will be provided to researchers for more extensive clinical studies after approval by the project implementers.

From where data/document is obtainable

Dr. Marjan Akbari Kamrani: dr.kamrani@goums.ac.ir Vice Chancellor for Research and Development of Golestan University of Medical Sciences: gsm@goums.ac.ir

What processes are involved for a request to access data/document

After sending an email to the mentioned authorities and reviewing the request by the project executors, the result will be notified to the applicant via email.

Comments