Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Effect of complementary supplementation Camelina Oil on the improvement of dry eye disease in patients with dry eye

Protocol summary

Study aim

1.Determination of the effect of camelina oil on schirmer test score 2.Determination of the effect of camelina oil 3.Determination of the effect of camelina oil on the degree of dry eye 4.Determining the effect of camelina oil on staining cornea

Design

Clinical trial with community based and pragmatic control group, with parallel groups, three strains of blind, simple random

Settings and conduct

clinical trial,third blind, 60 patients referred to the Eye Clinic Hospital Bina of Tehran - Iran will be selected randomly. Correlation includes: patient, questioner, data analyzer

Participants/Inclusion and exclusion criteria

inclusion criteria: 1. A moderate degree of dry eye 2. Ability to take oral capsules 3.Uploading consent form 4. Ability to re-examine for examination 5. People aged 18 to 65 years exclusion criteria: 1.The eye syringe test is less than 5 mm. 2. Eye TBUT is less than 5 seconds. 3. Excessive staining cornea 4. There is at least the corneal ulcer in that eye 5.Pregnancy or breastfeeding 6. Any eye surgery over the past 6 months in the affected eye 7. Any significant changes in diet during the last month or during the course of treatment 8. Contact lens consumers 9. Cortico-steroid and topical ointment use last month 10.Use of any oral supplement

Intervention groups

The first group received 2 capsules of 5 grams of canola oil daily and the second group received 2 grams of 5 grams of paraffin oil per day

Main outcome variables

Schirmer test, Tear Break Up Time, The degree of dry eye of the questionnaire, the mean staining corne, lipid profiles

General information

Reason for update

It needs to be updated due to changes

Acronym

IRCT registration information

IRCT registration number: **IRCT20180806040722N1**
Registration date: **2019-04-22, 1398/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-09, 1401/02/19**
Update count: **1**

Registration date

2019-04-22, 1398/02/02

Registrant information

Name

Mahdieh Reyhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3384 4624

Email address

mahdieh.reyhani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

2018-09-01, 1397/06/10

Actual recruitment end date

2019-12-01, 1398/09/10

Trial completion date

2019-12-01, 1398/09/10

Scientific title
Effect of complementary supplementation Camelina Oil on the improvement of dry eye disease in patients with dry eye

Public title
Effect of complementary supplementation Camelina Oil on the improvement of dry eye disease in patients with dry eye

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with moderate dry eye Ability to take oral capsules Fill in the consent form Ability to visit for examination

Exclusion criteria:
Eye shirmer test less than 5 mm TBUT eyes less than 5 seconds Excessive corneal opacification The presence of corneal ulcer at least in that eye Pregnancy or breastfeeding Corticosteroid use or systemic anti-inflammatory treatment simultaneously Taking any oral supplement A clear change in diet during the last month or during treatment Any eye surgery over the past 6 months in the affected eye

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **50**
Actual sample size reached: **47**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method, unit will be used individually and random numbers will be used

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants have a blinded role after informed consent, clinical care and outcome assessment

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tabriz University of Medical science

Street address
Central Organization2., Research Deputy., Univercity of Tabriz,

City
Tehran

Province
Tehran

Postal code
3357314

Approval date
2019-01-27, 1397/11/07

Ethics committee reference number
IR.TBZMED.REC.1397.890

Health conditions studied

1

Description of health condition studied
moderate dry eye

ICD-10 code
H04.1

ICD-10 code description
Other disorders of lacrimal gland Dacryops Dry eye syndrome

Primary outcomes

1

Description
schirmer test

Timepoint
5-10 mm

Method of measurement
Paper tape of schirmer

2

Description
tear break up time

Timepoint
5-10 second

Method of measurement
Coloring with fluorescein

Secondary outcomes

empty

Intervention groups

1

Description
Control group1: Capsule containing Comelina Oil, 0.5

grams, twice a day, 3 months, accompanied by breakfast and lunch, Vegeterian Company Barich Esanse

Category

Treatment - Drugs

2

Description

Control group2: Capsule containing paraffin oil, 0.5 grams, twice a day, 3 months, accompanied by breakfast and lunch ,Vegeterian Company Barich Esanse

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

vision health research center

Full name of responsible person

Khosrow Jadidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

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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

Iranian academic center for education culture and research

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

UN agencies and international organizations

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahdieh Reyhani

Position

Master

Latest degree

Master

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

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

Statistical Analysis Plan
Not applicable

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable