Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the effect of saffron extract and vitamin A supplement in the control and treatment of dry eye symptoms in patients referred to the Visual Health Center

Protocol summary

Study aim

Suggesting saffron and vitamin A supplements as a method of controlling and treating dry eye disease, as well as ultimately reducing the possible complications and costs of using other existing treatment methods if the research is successful and based on the research results.

Design

Saffron supplement in doses of 70 mg per day with 1 mg of vitamin A, the second group will receive saffron supplement 70 mg per day, the third group will receive vitamin A supplement of 1 mg per day for 3 months in the experimental groups, respectively. A placebo will also be obtained for 3 months in the control group. All groups, including the placebo group, will receive the usual treatment, including artificial tear drops.

Settings and conduct

Visual Health Research Center of Semnan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients with dry eye. Thus, if a person has a Shirmer 1 test (or SMTUBE) (with anesthesia) less than 10 mm and a tear film rupture test (TBUT) less than 10 seconds, it is a diagnosis of dry eye and will be included in the study. Exclusion criteria for previous eye surgery will be any eye disease, any systemic disease, and the use of contact lenses, both hard and soft.

Intervention groups

Saffron supplement in doses of 70 mg per day with 1 mg of vitamin A, the second group of saffron supplement 70 mg per day, the third group of vitamin A supplement 1 mg per day will be received for 3 months in the experimental groups, respectively. a placebo drug including 15 mg of magnesium stearate and 100 mg of maltodextrin will be used in combination with microcrystalline cellulose.

Main outcome variables

Each of the parameters obtained from the examination of the tear film of patients (dry eye, tear height and quality of life of patients with dry eye)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210926052587N1**
Registration date: **2022-07-16, 1401/04/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-16, 1401/04/25**
Update count: **0**

Registration date

2022-07-16, 1401/04/25

Registrant information

Name

Mohammad Mehdi Johari Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8878 5273

Email address

mohamadmehdi.jm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of saffron extract and vitamin A supplement in the control and treatment of dry eye symptoms in patients referred to the Visual Health Center

Public title

Evaluation of the effect of saffron extract and vitamin A supplement in the control and treatment of dry eye symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria are patients with dry eye. Thus, if a person has a Schmermer test (or SMTUBE) (with anesthesia) less than 10 mm and a tear film rupture test (TBUT) less than 10 seconds, it is a diagnosis of dry eye and will be included in the study.

Exclusion criteria:

Previous history of eye surgery Previous history of eye disorders Systemic disorders Using a contact lense (including soft or hard type) Failure to fill out the informed consent form

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using the Random number generation plugin in excel software, a table of random numbers from 1 to 1000 is prepared in an incoherent and scattered manner, and the numbers are assigned to four groups of 30 people by intervention and control software. The randomization process is studied by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 1000.

Blinding (investigator's opinion)

Double blinded

Blinding description

one ‘active’ pill and one ‘placebo’ pill. As they are physically identical, it is impossible for patients and researchers to discern which pill is the active one based on appearance alone.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences and Health Services

Street address

Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.

City

Semnan

Province

Semnan

Postal code

35147-99442

Approval date

2021-12-09, 1400/09/18

Ethics committee reference number

IR.SEMUMS.REC.1400.025

Health conditions studied

1

Description of health condition studied

Dry eye syndrome

ICD-10 code

H04. 129

ICD-10 code description

Dry eye syndrome of unspecified lacrimal gland

Primary outcomes

1

Description

Dry eye (in the present study, dry eye based on the results of the Surface Eye Disease Index (OSDI≥13) and TBUT non-invasive (less than 10 seconds), Shermer 1 test (with anesthesia) less than 10 mm and color Eye surface plasticity (OSS) will be defined (color>> 5 corneal points and> 9 conjunctival or eyelid edge points).

Timepoint

Measurement of dry eye at the beginning of the study (before the intervention) and 90 days after the start of medication

Method of measurement
(in the present study, dry eye based on the results of the Surface Eye Disease Index (OSDI≥13) and TBUT non-invasive (less than 10 seconds), Shermer 1 test (with anesthesia) less than 10 mm and color Eye surface plasticity (OSS) will be defined (color>> 5 corneal points and> 9 conjunctival or eyelid edge points).

Secondary outcomes

1

Description
best corrected visual acuity
Timepoint
Day 0 and Day 90
Method of measurement
Snellen chart

Intervention groups

1

Description
30 patients are randomly assigned to the control group and receive placebo for 90 days or 3 months. Each placebo capsule contains 35 mg of microcrystalline cellulose, maltodextrin and magnesium stearate. The usual placebo group will receive artificial tears. The capsules are prepared by Sina Pajouhan Salamat Pharmaceutical Company. Each group of volunteers receives standardized doses under the supervision of specialists. And the method of consumption is one capsule every 12 hours. For each volunteer participating in the study, a training session will be conducted to review the objectives of this study, interventions and follow-up and treatment will be done on day zero. Participants can also contact the patient follow-up officer (Mohammad Mehdi Johari Moghadam) during the study. Take the necessary follow-up. The course will last 90 days and the results of the study will be shared with all patients at the end of the study.
Category
Placebo

2

Description
Intervention group: First (second group of saffron supplement 70 mg per day) - 30 patients are randomly placed in intervention group 1 and receive the capsule for 90 days or 3 months. Each capsule contains 35 mg of saffron, which will be used orally and one capsule every 12 hours.
Category
Treatment - Drugs

3

Description
Intervention group: Second (vitamin A supplement one mg per day) 30 patients are randomly assigned to the second intervention group and receive the capsule for 90 days or 3 months. Each capsule contains 500 micrograms of vitamin A.
Category
Treatment - Drugs

4

Description
Third intervention group (vitamin A supplement of one mg with saffron 70 mg per day): 30 patients are randomly placed in the third intervention group and receive the capsule for 90 days or 3 months. Each capsule contains 500 micrograms of vitamin A and 35 mg (70 mg per day) of saffron. Capsules will be taken orally and one capsule every 12 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vision Health center of Tehran
Full name of responsible person
Khosrow Jadidi
Street address
Unit 17, 5th Floor, No. 8, 2nd alley, in front of Dey Hospital, above Tavanir Intersection, Valiasr St., Tehran
City
Tehran
Province
Tehran
Postal code
1516747418
Phone
+98 21 8819 6871
Email
mohamadmehdi.jm@gmail.com
Web page address
https://visionhealth.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Majid Mir Mohammad Khani
Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.
City
Semnan
Province
Semnan

Postal code
3514799442
Phone
+98 23 3345 2199
Email
majidmirmohammadkhani@yahoo.com
Web page address
https://semums.ac.ir/

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Semnan 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
The Vision Health Center of Tehran, Iran
Full name of responsible person
Khosrow Jadidi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Unit 17, 5th Floor, No. 8, 2nd alley, in front of Dey Hospital, above Tavanir Intersection, Valiasr St., Tehran
City
Tehran
Province
Tehran
Postal code
1516747418
Phone
+98 21 8819 6871
Email
kh.jadidi@gmail.com
Web page address
https://visionhealth.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Johari Moghadam
Position
General Physician
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
mohamadmehdi.jm@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Johari Moghadam
Position
General Physician
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran,
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
mohamadmehdi.jm@gmail.com

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
Not applicable

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

Title and more details about the data/document

The results of the data will be shared with the participants after the study and analytical review

When the data will become available and for how long

Access is allowed from the beginning of 2022

To whom data/document is available

Researchers in the field of ophthalmic surgery

Under which criteria data/document could be used

Adequate knowledge and previous background in ophthalmic research

From where data/document is obtainable

Mohammad Mehdi Johari Moghaddam Email address: Mohamadmehdi.jm@gmail.com

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

Request an email and send a resume and reason

Comments