Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Evaluation of the Effect of Oral Vitamin E on Dry Eye; A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of Vitamin E supplement on dry eye

Design

This study is a clinical trial with control group and parallel groups, double blind and randomized, each group consists of 45 patients were allocated in blocks of 6 patients in each one.

Settings and conduct

The population of the study includes patients aged 18-60 years with a dry eye disease. Ocular Surface Disease Index questionnaire is used to measure symptoms of patients with dry eye. Clinical tests implemented in the study include Tear Break Up Time and SMtube tests. Scores of these three tests are compared before and after the intervention. Patients are unaware of the existence of two types of intervention (Experiment group is receiving vitamin E supplement and artificial tear drop, and control group is receiving only artificial tear drops), also medical administrators (researcher and the ophthalmologist) and data analyzers are unaware of the type of intervention the patients are going to receive and the vitamin E supplement will be provided to them by a mediating agent.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients with Dry eye and questionnaire score above 10, TBUT test below 10 sec, and SM Tube test below 5 mm. - Age range of 18-60 years - Ability and consent of the patients to take part in the study - Non pregnant female participants Exclusion criteria: - Allergic or reaction history of taking vitamin E - History of blood coagulation disease - History of taking vitamin E supplement over the past 3 months

Intervention groups

- Experiment group are receiving artificial tear drop three times a day (every 8 hours) and vitamin E supplement (400 IU) along with their meal for better absorption for 14 days. - Control group are receiving only artificial tear drop three times a day (every 8 hours)

Main outcome variables

- Amount of tear secretion - Tear break up time - Dry eye symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190929044926N1**
Registration date: **2019-10-09, 1398/07/17**
Registration timing: **prospective**

Last update: **2019-10-09, 1398/07/17**
Update count: **0**

Registration date

2019-10-09, 1398/07/17

Registrant information

Name

Parisa Moslemi Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6684 7179

Email address

parisamoghadam@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2019-12-11, 1398/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Oral Vitamin E on Dry Eye; A Randomized Clinical Trial

Public title

Effect of Vitamin E on Dry eye

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Dry eye syndrome and questionnaire score above 10 TBUT test below 10 sec. SM Tube test below 5 mm. Age range of 18-60 years Ability and consent of the patients to take part in the study Non pregnant female participants No allergic or reaction history of taking vitamin E No history of blood coagulation disease No history of taking vitamin E supplement over the past 3 months

Exclusion criteria:

Patients with allergic or any kind of reactions with taking vitamin E Patients with blood disorders/coagulation problems Surgery history of Refractive errors

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in this study is Block Randomization and 15 blocks of 6 in each are implemented. In this method the number of individuals in each group will be the same and blocks are formed based on 2 variables (each block contains 6 variables which half of them is shown with an A letter that means receiving only artificial tear drop and the other half shown with B letter are going to receive vitamin E supplement and artificial tear drop). According to the main purpose of this method which is balancing the individuals in each group, patients will be matched based on their age, sex and severity of dry eye and with the help of a statistics software are divided into experiment and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Despite the fact that there is no placebo in this study, patients are unaware of the existence of two types of intervention (Experiment group is receiving vitamin E supplement and artificial tear drop, and control group is receiving only artificial tear drops), also medical administrators (researcher and the ophthalmologist) and data analyzers are unaware of the type of intervention the patients are going to receive and the vitamin E supplement will be provided to them by a mediating agent.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Emam Hosein Square, Damavand Street

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2019-07-21, 1398/04/30

Ethics committee reference number

IR.SBMU.REC.1398.044

Health conditions studied

1

Description of health condition studied

Dry eye

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Amount of tear secretion

Timepoint

Evaluating the amount of tear secretion in the beginning of the study and two weeks after the intervention is done.

Method of measurement

Evaluating with Strip Meniscometry Test (SMTube)

2

Description
Tear Break Up Time
Timepoint
Evaluating the Tear Break Up Time in the beginning of the study and two weeks after the intervention is done.
Method of measurement
Evaluating with TBUT (Tear Break Up Time) test

3

Description
Symptoms of Dry eye
Timepoint
Evaluating the symptoms of Dry eye in the beginning of the study and two weeks after the intervention is done.
Method of measurement
Evaluating with Ocular Surface Disease Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One capsule of Vitamin E supplement (in dosage of 400IU per day) with lunch and artificial tear drop named Tear-i (produced in Alborz Daru Company) which contains 1/4 gram Polyvinyl alcohol per 100 milliliter every 8 hours one drop in each eye for 14 days
Category
Treatment - Drugs

2

Description
Control group: Artificial tear drop named Tear-i (produced in Alborz Daru Company) which contains 1/4 gram Polyvinyl alcohol per 100 milliliter every 8 hours one drop in each eye for 14 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Payambaran Hospital
Full name of responsible person
Parisa Moslemi Moghadam
Street address
Ayatollah Kashani Blv. Abazar Blv. Payambaran Hospital
City
Tehran
Province
Tehran
Postal code
۱۴۷۱۷۵۵۱۱۱
Phone
+98 21 4407 9131
Email
Info@payambaranhospital.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Afshin Zarghi
Street address
Emam Hosein Square, Damavand Blv.
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7756 1724
Email
Info@sbmu.ac.ir
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
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parisa Moslemi Moghadam
Position
MSC Student
Latest degree
Bachelor
Other areas of specialty/work
Optometry
Street address

Emam Hosein Square, Damavand Street

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 21 6684 7179

Email
Parisamoghadam95@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parisa Moslemi Moghadam

Position
MSC Student

Latest degree
Bachelor

Other areas of specialty/work
Optometry

Street address
Emam Hosein Sq, Damvand Street

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 21 6684 7179

Email
Parisamoghadam95@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parisa Moslemi Moghadam

Position
Optometrist

Latest degree
Bachelor

Other areas of specialty/work
Optometry

Street address
Emam Hosein square, Damamvand street, School of Rehabilitation of Shahid Beheshti

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
+98 21 6684 7179

Fax

Email
parisamoghadam@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data from questionnaires and results of the tests

When the data will become available and for how long
Accessibility period will be 3 months after publishing the results

To whom data/document is available
Researchers working at scientific institutions

Under which criteria data/document could be used
Refering to the reference of data

From where data/document is obtainable
Parisa Moslemi Moghadam Email: parisamoghadam95@yahoo.com Phone number: 00989189730753

What processes are involved for a request to access data/document
Sending the request of receiving data and waiting for the result till at least 1 month later

Comments