

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Evaluation of Almond-Viola odorata oil efficacy in dry eye disease, placebo-control, double blind randomized clinical trial

#### Protocol summary

##### Summary

The main purpose of this randomized double-blind clinical trial study, is to evaluate the effect of Almond-Viola odorata oil on treatment of dry eye. 90 Patients (18-60 years old) with the complaint of dryness or foreign body in eye, eye burning, or photo phobia referred to Hazrat Rasoul Akram hospital, will be included in our study provided that have the following criteria: a- TUBT score, after 3 times of sequential measurement become less than 10 seconds: Schirmer test without topical anesthesia at least in one eye during 5 minutes become less than 10 millimeters: coloring cornea with flourocin at least in one eye. These patients will be assessed and the following scores will be recorded for each one: Score gained on OSDI questionnaire. The score of Schirmer test. Average time of TBUT. Then the patients will be divided into 3 groups by the randomized block method. The patients in each group will receive nasal drop of Almond-Viola odorata oil or almond oil or placebo (two drop three times a day). After 4 weeks, the patients will be visited again and the tests in the first visit will be repeated. patients, researcher will be blind

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016020626398N1**

Registration date: **2016-02-19, 1394/11/30**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-02-19, 1394/11/30

##### Registrant information

###### Name

Aniseh saffarshahroodi

##### Name of organization / entity

Shiraz University of Medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3234 7966

##### Email address

a-saffar@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Almond-Viola odorata oil efficacy in dry eye disease, placebo-control, double blind randomized clinical trial

##### Public title

Almond-Viola odorata oil efficacy in dry eye disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: complaint of foreign body or dry eye and at least in one eye; TUBT score for 3 times after sequential measurements become less than 10 seconds or Schirmer test without topical anesthesia at least in one eye during 5 minutes become less than 10

millimeters or coloring cornea with flourocin at least in one eye; age 18-60 years old; ability to use nasal drop; complete the informed consent form; ability to come for follow up. Exclusion criteria: the Schirmer test be less than 5 millimeters ; TUBT test be less than 5 seconds ;severe corneal coloring ;corneal ulcer at least in that eye ; filamentous keranopathy in that eye ;pregnancy or breast feeding ;any eye Surgery in the last 6 months ;any change in diet in the last month or during treatment ;the use of any topical eye drug during last 7 days in the affected eye ; patients who use topical eye drug due to another eye disease ;people who use contact lens ;use of corticosteroid in the last month ;use of anti-inflammatory drug for eye during last month ;use of corticosteroid or systemic anti-inflammatory drug Simultaneously with treatment ;use of any edible supplement

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

**Street address**

Zand St.

**City**

Shiraz

**Postal code****Approval date**

2016-01-24, 1394/11/04

**Ethics committee reference number**

IR.SUMS.REC.1394.173

**Health conditions studied****1****Description of health condition studied**

Dry eye

**ICD-10 code**

H04.1

**ICD-10 code description**

Other disorders of lacrimal gland

**Primary outcomes****1****Description**

Foreign body sensation, photophobia, blur vision, Burning

**Timepoint**

Baseline,4weeks after starting the medication

**Method of measurement**

Filling OSDI questionnaire

**2****Description**

Tear Break Up time

**Timepoint**

Baseline,4weeks after starting the medication

**Method of measurement**

The time that takes for the first dry spot to appear following blinking after fluorescein instillation

**3****Description**

tear secretion

**Timepoint**

Baseline,4weeks after starting the medication

**Method of measurement**

measurement Schirmer test- Wetting of the filter paper after 5 minutes

**4****Description**

Tear osmolarity

**Timepoint**

Baseline,4 weeks after starting the medication

**Method of measurement**

Tear osmolarity maesurment via TearLab device- miliosmol /lit

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention :Nasal drop(15ml) contain of Almond-Viola odorata oil, 3 times a day, every time 2 drop in each nostril for 4 weeks.

**Category**

Treatment - Drugs

**2****Description**

Control:Nasal drop(15ml) contain of placebo, 3 times a day, every time 2 drop in each nostril for 4 weeks.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hazrat Rasool General Hospital

**Full name of responsible person**

DR Aniseh saffarShahroodi

**Street address**

Niayesh St. Satarkhan Ave.

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research of Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Basir Hashemi

**Street address**

Zand St.

**City**

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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**

Vice chancellor for research of Shiraz University of Medical Sciences

**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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Aniseh saffarShahroodi

**Position**

M.D./PhD candidate of Traditional Medicine

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences, Eye Research Center

**Full name of responsible person**

Dr Hossein Aghaee

**Position**

Ophthalmologist-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*