

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

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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.

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Shiraz

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

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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

Ophtalmologist-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