Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of intra nasal viola odorata almond oil drop on dry eye disease

Protocol summary

Study aim
Evaluation the effectineness of viola odorata almond oil nasal drop on eye dryness
Design
Randomized, parallel group clinical trial with double blinded
Settings and conduct
Negah hospital -Mostafa Khomeini hospital The patient, the prescribe, as well as the person who analyze the data, do not know the type of treatment
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- age between 30 to 70 years 2- Tear Break Up Time less than 10 seconds at least in one eye 3- schirmer test less than 10 mili meter at least in one eye without Local anesthesia 4- 2 symptoms of feeling eye dryness , foreign body sensation , eye burning Exclusion criteria : 1-Any active eye infection 2- Pregnancy or Lactation 3- Any anatomic disorder like entropion or ectropion 4-incoordination of patients 5- important surface diseases of eyes which affects test results 6-History of eye trauma during the past 2 months 7-Moderate to severe blepharitis 8-Refraction surgery or laser therapy of eyes during the past month
Intervention groups
Intervention group: Daily treatment with artificial tear and viola odorata almond oil drop intranasal 2 drops in each nostril at night before sleeping category : Treatment - Drugs Control group: Daily treatment with artificial tear and Normal Saline drop intranasal 2 drops in each nostril at night before sleeping Category : Placebo
Main outcome variables
Eye dryness based on the score of questionaire

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181028041487N1**
Registration date: **2019-01-28, 1397/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-28, 1397/11/08**
Update count: **0**
Registration date
2019-01-28, 1397/11/08

Registrant information
Name
jamshid shayanfar
Name of organization / entity
Shahed university
Country
Iran (Islamic Republic of)
Phone
+98 21 4470 9236
Email address
shayanfarj@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2019-02-19, 1397/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of intra nasal viola odorata almond oil drop on dry eye disease

Public title

Evaluation the effect of intra nasal viola odorata almond oil drop on dry eye disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 30 to 70 years TBUT<10 s at least in one eye schirmer test < 10 mm at least in one eye without Local anesthesia 2 symptoms of feeling eye dryness , foreign body sensation, eye burning

Exclusion criteria:

Any active eye infection Pregnancy or Lactation Any anatomic disorder like entropion or ectropion incoordination of patients important surface diseases of eyes which affects test results History of eye trauma during the past 2 months Moderate to severe blepharitis Refraction surgery or laser therapy of eyes during the past month

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are categorized to two groups A&B respectively based on attendance . The first female patient is allocated in group A and the second female patient is allocated in group B. Male patients also are allocated in two groups in a same way.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding of drops is done by safety and data supervision committee. Patients (treatment and control group) and the practitioner are blind about the interventions and administered drops.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahed university

Street address

Beginning of Tehran Qom freeway-Shahed university

City

Tehran

Province

Tehran

Postal code

1865133191

Approval date

2017-12-26, 1396/10/05

Ethics committee reference number

IR.Shahed.REC.1396.72

Health conditions studied

1

Description of health condition studied

EYE DRYNESS

ICD-10 code

H04.12

ICD-10 code description

Primary outcomes

1

Description

EYE DRYNESS

Timepoint

At the beginning of the study - After 3 weeks - After 6 weeks

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They get viola odorata almond oil 2 drops intra nasal for 6 weeks. Both placebo and drug are produced by Traditional medicine research center of Shahed university.

Category

Treatment - Drugs

2

Description

Control group: They get Normal Saline 2 drops intra nasal for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Negah hospital - Mostafa Khomeini hospital

Full name of responsible person
Dr Hassan Ghasemi

Street address
No. 3,Gol Nabi Ave., Ketabi Sq.,Negah hospital AND Italia Ave., Mostafa Khomeini hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
Dr Ali Davati

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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
Shahed University

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
Shahed University

Full name of responsible person
Dr Jamshid Shayanfar

Position
pHD student

Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Person responsible for updating data

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Latest degree
Medical doctor

Other areas of specialty/work
Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

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