Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Investigating the effect of Viola Odorata eye drop on dry eye disease: a randomized clinical trial

Protocol summary

Study aim
Determining the effect of Violet flower extract on improving the symptoms of patients with dry eye disease

Design
A 3-blind, placebo-controlled, parallel-group, randomized, phase 3 clinical trial in 52 patients. Randomization is done with random number table and Random Allocation Software.

Settings and conduct
Patients with dry eye symptoms are examined and diagnosed by an ophthalmologist at Khatam Al Anbia Hospital or private office in Mashhad. Clinical examinations and imaging are performed in order to determine the degree of dry eye using a keratograph. The OSDI and DEQ-5 questionnaires and brain temperament questionnaire are completed by the resident responsible for the project. The patients will be randomly divided into two groups: drug and placebo. 4 weeks later they are checked again by the specialist. In the intervals of 2 and 4 weeks after the intervention, the mentioned forms are completed again for all patients. All objective tests are repeated 4 weeks after intervention using the keratograph.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with complaints of dry eyes; Score of OSDI questionnaire more than 12 and DEQ-5 more than 6; Consent to treatment with herbal medicines; No active eye infection; No history of refractive surgery; Absence of pterygium disease; Not using medicines with dry eye side effect

Intervention groups
The intervention group received 15 cc eye drops containing water extract of violet flower (2 grams per hundred ml) and artificial tears, and the control group received 15 cc eye drops containing placebo and artificial tears.

Main outcome variables
Foreign body sensation, sensitivity to light, blurred vision, eye irritation Tear breakup time (TBUT), meniscus tear height, conjunctival redness and meibomian gland grade

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231013059708N1**
Registration date: **2023-11-25, 1402/09/04**
Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**
Update count: **0**

Registration date
2023-11-25, 1402/09/04

Registrant information

Name
Haleh Ghooshkhanei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3878 3310

Email address
halonik_md@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-01, 1402/10/11

Expected recruitment end date
2024-12-30, 1403/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Viola Odorata eye drop on dry eye disease: a randomized clinical trial

Public title
The effect of Viola drop on dry eye

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with complaints related to dry eye syndrome OSDI questionnaire score is more than 12 and DEQ5 is more than 6 Consent to treatment with herbal and traditional medicines No active eye infection No history of refractive surgery Absence of pterygium disease Not using drugs with dry eye complications

Exclusion criteria:
The patient's unwillingness to receive treatment Allergy to herbal medicines Pregnancy Breastfeeding

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method in this design will be block method. Blocks of 4 will be used and the sequence produced by the website https://www.sealedenvelope.com will be provided by the project methodologist and will be placed in closed, sealed, opaque and numbered envelopes and the researcher assistant opens one of the envelopes and the patient will be allocated to the group mentioned in the envelope.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug and placebo will be packed in the same cans, and only the code and method of administration will be written on them. The patient and specialist and the statistical analyst are unaware of the assigned codes, and at the end of the study, the code is decoded by an informed person. The participant, the researcher, the statistical analyst and Data Safety and Monitoring Committee are unaware of the arrangement of groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Ethics committee of Mashhad University of Medical sciences, central office of Mashhad University of Medical Sciences, Daneshgah Ave., Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2023-10-07, 1402/07/15

Ethics committee reference number
IR.MUMS.REC.1402.194

Health conditions studied

1

Description of health condition studied
Dry Eye Syndrome

ICD-10 code
H 04.1

ICD-10 code description
Tear film insufficiency, Meibomian gland dysfunction

Primary outcomes

1

Description
Dry Eye symptoms

Timepoint
Before the intervention, 2 weeks and 4 weeks after the intervention

Method of measurement
Completion of the OSDI and DEQ5 questionnaires

2

Description
Tear break time (TBUT)

Timepoint
Before the intervention and 4 weeks after the intervention

Method of measurement
The time of appearance of the first changes after the first

blink in seconds with the keratograph

3

Description
Tear meniscus height
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
The height of the lacrimal crescent using the Keratograph values

4

Description
Redness of the conjunctiva
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Using the Keratograph values

5

Description
Meibomian gland grade
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Morphological changes of meibomian glands using the Keratograph values

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Eye drops containing 15 cc of aqueous violet extract (two grams per hundred milliliters) for four weeks, one drop four times a day
Category
Treatment - Drugs

2

Description
Control group: Eye drops containing 15 cc of placebo for six weeks, one drop four times a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam al Anbia Eye Hopital
Full name of responsible person
Haleh Ghoushkhanei
Street address
Khatam al Anbia hospital, Shahid Gharani Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Phone
+98 51 3728 1401
Email
halonik_md@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi Pharm D.
Street address
Deputy of Research and Technology, Gharshi Building, Daneshgah St., Mashhad, Iran.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3881 4043
Email
TafaghodiM@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Haleh Ghooshkhanei
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Mashhad Faculty of Iranian and Complementary Medicine, University Campus, East Door, Azadi Square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3884 8931
Email
halonik_md@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Roshanak Salari, Pharm D.
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Mashhad Faculty of Persian and Complementary Medicine, University Campus, East Door, Azadi Square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3884 8930
Email
SalariR@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Haleh Ghooshkhanei MD.
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Mashhad Faculty of Persian and Complementary Medicine, University Campus, East Door, Azadi Square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3884 8931
Email
halonik_md@yahoo.com

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