Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Studying the effect of a new type of honey eye drop on dry eye in patients with dry eye

Protocol summary

Study aim
To determine the effect of 1 percent honey drops on the treatment of dry eye

Design
Clinical trial with control group, with parallel groups, Triple blinded and randomized using random number table , phase 3 on 80 patients.

Settings and conduct
80 dry eye patients referred to the Poostchi ophthalmology clinic will be included in the study and randomly assigned to two groups (treatment and control). Patients are treated with honey drops or routine treatment (artificial tear drops, as a control group) for 1month and are followed-up . The blinding of study will be Triple blinded and include patients, the doctor, and the data analyst.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with dry eye syndrome (regardless of age and sex) clinically diagnosed by ophthalmologist, Tear secretion test should be less than or equal to 5 mm, Tear break time is less than or equal to 10 seconds. Exclusion criteria: Blepharitis, meibomian disorder, history of tetracycline and oral corticosteroid use in the last 3 months, ocular surface disorders, history of previous surgery and allergies

Intervention groups
Intervention group: treatment with honey drops; including 1% honey (made from Gavan honey, produced by "Kandu Asal" company in Tearlose artificial tear drops), three times a day, one drop each time for one month. Honey drops will be prepared in the clean room of Shiraz University of Medical Sciences. Control group: standard treatment including Tearlose artificial tears, three times a day, one drop each time for one month.

Main outcome variables
Tear break-up time, Basic tear secretion rate, corneal staining

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220117053744N1**
Registration date: **2023-04-16, 1402/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-16, 1402/01/27**
Update count: **0**

Registration date
2023-04-16, 1402/01/27

Registrant information

Name
Mahmoud Nejabat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3230 2830

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nejabatm@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Studying the effect of a new type of honey eye drop on dry eye in patients with dry eye

Public title
Studying the effect of a new type of honey eye drop on dry eye patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients (male or female, without age limit) with dry eye syndrome (at three levels of low, moderate, and severe) Best corrected vision greater than or equal to 9/10 Schirmer test is less than 5 mm in 5 minutes Tear break time is less than 10 seconds
Exclusion criteria:
Patients with blepharitis disorder Patients with meibomian gland disorder Patients with a history of taking tetracycline for the past three months Patients with a history of taking oral corticosteroids for the past three months Patients with ocular surface disorders Patients with a history of previous surgery Patients with a history of allergies
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
We assigned patients a code from 1 to 80. Then we used a table of random numbers to select 40 numbers. For the 40 selected patients, the Honey eye drop was used for the treatment. In the other 40 patients, the (artificial tear) was used.
Blinding (investigator's opinion)
Triple blinded
Blinding description
First, informed consent was obtained from the patients .In order to blind, the desired drops are provided to patients in similar packages and in coded form, and patients will not be aware of the content of their medication. Patients will be aware that they will be randomly assigned to one of two treatment groups, but will be unaware of which treatment will be provided in that group. The physician also knows that patients will be anesthetized in two different ways, but will not know which procedure will be performed for each patient. The data collection officer, analyst and outcome assessor will collect and analyze information based on groups 1, 2 and will not be aware of the type of treatment provided in the groups. They will be kept blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research, Medical School -Shiraz University of Medical Sciences
Street address
No. 16, Zand Blvd., Shiraz
City
Shiraz
Province
Fars
Postal code
7134814336
Approval date
2022-01-09, 1400/10/19
Ethics committee reference number
IR.SUMS.MED.REC.1400.548

Health conditions studied

1

Description of health condition studied
dry eye syndrom
ICD-10 code
H04.1
ICD-10 code description
Other disorders of lacrimal gland

Primary outcomes

1

Description
Tear break up time (TBUT)
Timepoint
2, 4 and 6 weeks after starting treatment
Method of measurement
Clinical examination of the patient - per second

2

Description
Corneal staining
Timepoint
2, 4 and 6 weeks after starting treatment
Method of measurement
Clinical examination of the patient with Fluorescein test

3

Description
Basic tear secretion rate
Timepoint
2, 4 and 6 weeks after starting treatment
Method of measurement
Clinical examination of the patient - In millimeters per minute

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: treatment with honey drops (prepared from Gavan honey, produced by "Kandu Asal" company; 1% honey in Tearlose drops); Three times a day, one drop each time for one month, (routine treatment of dry eyes will not be removed for this group of patients)
Category
Treatment - Drugs

2

Description
Control group: Standard treatment includes artificial tears (Tearlose) three times a day, one drop each time for a month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Poostchi Ophthalmology Clinic, Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Khaki
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Shiraz University of Medical Sciences, Zand St. Shiraz
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mehdikhaki1989@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Mohammad Hashempoor
Street address
Vice Chancellor for Research, Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Khaki
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
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Person responsible for updating data

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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