

# 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)

##### Phone

+98 71 3230 2830

##### Email address

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

##### **Street address**

Shiraz University of Medical Sciences, Zand St. Shiraz

##### **City**

Shiraz

##### **Province**

Fars

##### **Postal code**

71348-14336

##### **Phone**

+98 901 043 0859

##### **Email**

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

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

+98 71 3235 7282

##### **Fax**

##### **Email**

Hashempurm@sums.ac.ir

#### **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

##### **Street address**

No. 196. Alley 41. North Motahhari Boulevard

##### **City**

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##### **Province**

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##### **Postal code**

71849-15133

##### **Phone**

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**Email**

mehdikhaki1989@yahoo.com

**Person responsible for scientific 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****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**

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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