# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effectiveness of umbilical cord blood serum on curing eye dryness

### Protocol summary

**Study aim**
Determining the effect of using diluted human umbilical cord blood serum in the treatment of dry eye

**Design**
Considering the following values and considering a 20% probability of sample loss, 32 samples or 64 eyes are ultimately required. Random assignment of patients to two groups is performed using the permuted block stratified randomization method.

**Settings and conduct**
Patients will first be examined by an anterior segment specialist and after confirmation of dry eye, treatment with artificial tears will be initiated, and one group will be given drops made from fetal cord blood and used simultaneously with artificial tears. The subjects will be randomly assigned to two treatment groups. After receiving the eye drops, patients will be followed up for 3 months.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Chronic dry eye (>3 months) unresponsive to standard treatment, with Schirmer I <5 mm, TBUT <5 s, or Oxford grade >3. Exclusion criteria: Age <18, pregnancy, contact lens use, recent ocular allergy or surgery (within 6 months), eyelid/eyelash abnormalities, and infectious diseases (HBV, HCV, HIV).

**Intervention groups**
Patients with dry eye disease will be randomly assigned to two groups. One group will receive artificial tears, while the other group will receive eye drops derived from fetal umbilical cord blood in combination with artificial tears. Patients will be followed for 6 months and assessed for visual acuity, dry eye questionnaire score, corneal sensitivity, tear breakup time, extent of corneal staining, tear meniscus height, and blink rate.

**Main outcome variables**
Visual acuity, dry eye score , corneal sensation assessment with an aesthetometer, tear breakdown time, corneal coloration extent, tear prism height, blinking frequency

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20250702066328N1**
Registration date: **2025-12-29, 1404/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-29, 1404/10/08**
Update count: **0**

**Registration date**
2025-12-29, 1404/10/08

**Registrant information**

**Name**
Mehraneh Jafari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 903 904 4175

**Email address**
mehranejafarimums@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-12-16, 1404/09/25

**Expected recruitment end date**
2026-03-16, 1404/12/25

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Investigating the effectiveness of umbilical cord blood serum on curing eye dryness

**Public title**

Investigating the effectiveness of umbilical cord blood serum on curing eye dryness

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients with dry eyes for more than 3 months that do not improve with conventional treatment (such as artificial tears or ointments) Patients with dry eye who have a Type I Schirmer test of less than 5 mm Dry eye patients with Oxford test scores greater than stage 3

**Exclusion criteria:**

Age under 18 years Pregnancy Use of contact lenses History of ocular allergy, intraocular surgery, and/or refractive surgery within the past 6 months Anatomical changes of the eyelids and/or eyelashes Patients with infectious or transmissible diseases such as HBV, HCV, or HIV

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random assignment of patients to two groups is performed using the permuted block stratified randomization method. First, eligible patients are classified according to age and gender in the order of arrival. Then, they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two replications for each) that are randomly selected from all possible permutations. These blocks were created using R statistical software version 4.0.2. Matching: The two groups are matched in terms of age and sex using a stratified permutation block randomization method (frequency matching). Blinding: This study uses a single blinding method, so that the technician responsible for recording the outcomes will not be aware of the intervention in question.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study uses a single blinding method, so that the technician responsible for recording the outcomes will not be aware of the intervention in question.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences

**Street address**

Motahari Boulevard, Zahedan, Sistan and Baluchestan Province, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816737791

**Approval date**

2025-04-20, 1404/01/31

**Ethics committee reference number**

IR.ZAUMS.REC.1404.019

## Health conditions studied

### 1

**Description of health condition studied**

Dry eye

**ICD-10 code**

H04

**ICD-10 code description**

Disorders of lacrimal system

## Primary outcomes

### 1

**Description**

Determining and comparing average visual acuity in dry eye treatment

**Timepoint**

At the beginning of the study and the first and third months after the start of the diluted fetal umbilical cord blood serum drip

**Method of measurement**

It was measured based on the LogMAR method (Logarithm of the minimum angle of resolution).

### 2

**Description**

Determining and comparing the average dryness score in dry eye treatment

**Timepoint**

At the beginning of the study and one month and three months after starting the use of diluted fetal cord blood serum

**Method of measurement**

It is determined based on the OSDI questionnaire score and recorded in the information form.

**3**

**Description**
Corneal sensitivity
**Timepoint**
At the beginning of the study and one month and three months after starting the use of diluted fetal cord blood serum
**Method of measurement**
Corneal sensitivity

**4**

**Description**
Tear film break up time
**Timepoint**
At the beginning of the study and one month and three months after starting the use of diluted fetal cord blood serum
**Method of measurement**
tear film breakup time (Second)

**5**

**Description**
The height of the lacrimal prism
**Timepoint**
At the beginning of the study and one month and three months after starting the use of diluted fetal cord blood serum
**Method of measurement**
Tear meniscus height is measured using slit lamp examination and recorded on the information form.

**6**

**Description**
Blink frequency
**Timepoint**
At the beginning of the study and one month and three months after starting the use of diluted fetal cord blood serum
**Method of measurement**
It is determined based on blink rates (25%, 50%, 75% blinks, All lid closures, Extended lid closures, and Superextended lid closures) and recorded in the information form.

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention Group:Patients in this group will receive eye drops prepared from diluted human umbilical cord blood serum in combination with standard artificial tears. The cord blood serum is diluted to a specific concentration and prepared under sterile conditions. Patients will instill one drop in each eye four times daily. The treatment duration is 6 months, with regular follow-up visits to assess the effect on visual acuity, dry eye questionnaire score, corneal sensitivity, tear breakup time, extent of corneal staining, tear meniscus height, and blink rate.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: Patients in this group will receive only standard artificial tears, instilled one drop in each eye four times daily. The follow-up schedule and assessment parameters are the same as in the intervention group.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Alzahra Ophthalmology Hospital
**Full name of responsible person**
Mehraneh Jafari
**Street address**
Motahari Boulevard, Zahedan, Sistan and Baluchestan Province, Iran
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816737791
**Phone**
+98 903 904 4175
**Email**
Mehranejafarimums@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Zahedan University of Medical Sciences
**Full name of responsible person**
Alireza Ansari Moghaddam
**Street address**
Motahari Boulevard, Zahedan, Sistan and Baluchestan Province, Iran
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
9816737791
**Phone**

+98 903 904 4175

**Email**

Mehranejafarimums@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zahedan 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**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mehraneh Jafari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ophthalmology

**Street address**

Motahari Boulevard, Zahedan, Sistan and Baluchestan Province, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816737791

**Phone**

54333372113

**Email**

Mehranejafarimums@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mohammadhossein Validad

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

Motahari Boulevard, Zahedan, Sistan and Baluchestan Province, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816737791

**Phone**

+98 54 3337 2113

**Email**

Mhovalidad@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Mehraneh Jafari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Ophthalmology

**Street address**

Motahari Boulevard, Zahedan, Sistan and Baluchestan Province, Iran

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816737791

**Phone**

+98 903 904 4175

**Email**

Mehranejafarimums@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Some of the information related to the main outcome, such as age, gender, and level of education, will be shared temporarily.

**When the data will become available and for how long**

Access period begins after results are printed.

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Researchers working in academic and scientific institutions

**From where data/document is obtainable**

email:mehranejafarimums@gmail.com

**What processes are involved for a request to access data/document**

Providing job information, educational qualifications, and the reason for requesting the file

**Comments**