

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the Effectiveness of Three Methods of eye care in the prevention of keratitis disorders In patients (ICU)

#### Protocol summary

##### Study aim

Comparison of three methods of ophthalmology in prevention of keratitis in ICU patients

##### Design

Triple blind with parallel groups

##### Settings and conduct

Study population and characteristics of the study. Patients admitted to ICU wards with lower consciousness level of 8. Less than 8) There is no history of eye problems in the patient's history. Patients undergoing ophthalmic examinations with blue light ophthalmoscopy and fluorescein testing will also be included when entering the ward if the cornea is healthy and without any other eye problems, as well as examination and examination of the patient's condition by the study physician. The patient will be placed in one of the eye care groups by simple random method (throwing dice). Place of Study: Shahid Sadoughi Hospital of Yazd Intensive Care Unit

##### Participants/Inclusion and exclusion criteria

Patients hospitalized in intensive care units Exclusion: Patients whose fluorescein test is positive at admission. Patients with trauma or injury. Entry requirements: Patients with decreased consciousness below 8. Connect to the ventilator. Impaired blink reflex.

##### Intervention groups

The patient will be assigned to one of the eye care groups by simple random method (Roll of a die). In this case, the number (comparison of the eye ointment and the anti-allergic glue), ( the eye and artificial tears ), ( Comparison of Anti-Allergenic Tape and Artificial Tears) Each patient will receive two care modes such that one eye will receive simple eye ointment and the other one will receive anti-allergic glue, thereby confounding the effects. Each patient's eye will receive eye care for 6 hours and then receive simple eye care, including washing with distilled water and cotton.

##### Main outcome variables

ocular keratitis.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200204046370N1**

Registration date: **2020-04-13, 1399/01/25**

Registration timing: **retrospective**

Last update: **2020-04-13, 1399/01/25**

Update count: **0**

##### Registration date

2020-04-13, 1399/01/25

##### Registrant information

##### Name

Elham Fazljoo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3235 8700

##### Email address

e.fazljoo@ssu.ac

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-21, 1397/03/31

##### Expected recruitment end date

2019-02-28, 1397/12/09

##### Actual recruitment start date

2018-06-21, 1397/03/31

##### Actual recruitment end date

2019-02-28, 1397/12/09

##### Trial completion date

2019-05-20, 1398/02/30

##### Scientific title

Comparing the Effectiveness of Three Methods of eye care in the prevention of keratitis disorders In patients (ICU)

#### Public title

Comparing the Effectiveness of Three Methods of eye care in the prevention of keratitis disorders In patients (ICU)

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with decreased consciousness below 8. Connect the ventilator Impaired blink reflex Age over 18 years

##### Exclusion criteria:

Patients with eye damage at admission Patients who have had a history of diabetes and hypertension Patients whose fluorescein test is positive at admission Patients with trauma or injury.

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Different eye care in each patient's eye

Actual sample size reached: **60**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Different eye care in each patient's eye

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Simple randomization is used. Roll OF a die was used. So that the numbers 1 and 4 methods of eye ointment and anti-allergic adhesive, Numbers 2 and 5 Ophthalmic ointment and anti-allergic adhesive, Numbers 3 and 6 had anti-allergic adhesive and artificial tears. The randomization unit has also been individualized. Initially, any patient that entered the special ward ,examined by a specialist ICU physician and Inclusion and exclusion criteria were evaluated. If the patient met the inclusion criteria The patient was assigned to one of the treatment groups by roll of a die By a researcher . Then the eye care was done by another researcher and an eye examination was performed by an ophthalmologist. In order to conceal the throwing of the dice, it was done by the secretary who did not know the type of treatment in the groups, so that when the disease was accepted and approved by a special care specialist to attend the study, the secretary who was not part of the research team Throwing a dice determined which group the patient was in and informed the researcher It didn't happen random layers and

random sequences.

#### Blinding (investigator's opinion)

Triple blinded

#### Blinding description

The subjects in this study were comatose patients. So they were not aware of their eye care. The person doing the eye care was a researcher .But the eye examination was done by an ophthalmologist who was not aware of the type of eye care. In this way, before the start of the eye examination, the type of care was cleared from the patient's eye. And the one who did the data analysis It only had group numbers And the type of care provided in each group was not known.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Nothing

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Yazd of Medical Sciences

##### Street address

No. 5, Fifth Alley, Shahd Zinly Alley, Fajr Dahi Boulevard

##### City

Yazd

##### Province

Yazd

##### Postal code

8914946819

#### Approval date

2017-01-10, 1395/10/21

#### Ethics committee reference number

IR.SSU.REC.1395.207

## Health conditions studied

### 1

#### Description of health condition studied

Keratitis

#### ICD-10 code

H16.0

#### ICD-10 code description

Corneal ulcer

## Primary outcomes

### 1

#### Description

Ocular keratitis

## Timepoint

At the beginning of the study and on the seventh day

## Method of measurement

Fluorescein Test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Ointment and anti-allergenic adhesive. Ointment care :Every 6 hours by a trained nurse investigator in one of the patient's eyes about 2 cm of ointment in the inferior fornix from the inside out with the sterilization technique, so that about 1 cm of the ointment is poured out at the beginning of the ointment and Avoid contact with the patient's eye ointment and have the nurse thoroughly wash their hands as well as any ointment specific to the patient. After pouring the ointment, the patient's eyes are gently closed and checked every two hours by the nurse for the eyelid to be closed. Every 6 hours the patient's eyes are washed by the nurse with sterile water and cotton. Care with anti-allergic adhesive (1 / 25cm wide)Every 6 hours, the eyelid is closed with an anti-allergic adhesive with a width of 1.27. In such a way that one piece of adhesive is placed horizontally on the upper eyelid and the other piece is placed vertically on the patient's eyelid so that it rests on the patient's cheek and eyelid. Examines in terms of damage. If the adhesive needs to be renewed, this will be done. Every 6 hours the patient's eyes will be rinsed with sterile water and cotton and the eye care will be re-applied.Eye care was performed 3 times every 24 hours. Eye care was performed at night.Consumption of sterile plain eye ointment 3.5 g (Lubratex): (lanolin content 10%, white platelet 80% and mineral oil 10%).CompanySina Daroo Tehran.Anti-allergic adhesive with width: 1/27.Company Sins Max

#### Category

Prevention

### 2

#### Description

Intervention group: Intervention group 1: Ointment and artificial tear. Ointment care :Every 6 hours by a trained nurse investigator in one of the patient's eyes about 2 cm of ointment in the inferior fornix from the inside out with the sterilization technique, so that about 1 cm of the ointment is poured out at the beginning of the ointment and Avoid contact with the patient's eye ointment and have the nurse thoroughly wash their hands as well as any ointment specific to the patient. After pouring the ointment, the patient's eyes are gently closed and checked every two hours by the nurse for the eyelid to be closed. Every 6 hours the patient's eyes are washed by the nurse with sterile water and cotton.Another patient's eye care was performed with artificial tears. That is, every 6 hours the nurse in charge trained by the

researcher washes her hands and pours artificial tears into the other eye. For further care of the patient's eyes, the nurse is rinsed with sterile water and cotton, and the procedure is repeated again..Eye care was performed 3 times every 24 hours. Eye care was performed at night.Consumption of sterile plain eye ointment 3.5 g (Lubratex): (lanolin content 10%, white platelet 80% and mineral oil 10%).CompanySina Daroo Tehran.Sina Darou Tehran Artificial Tears

#### Category

Prevention

### 3

#### Description

Intervention group:anti-allergenic adhesive and artificial tear. Care with anti-allergic adhesive (1 / 25cm wide)Every 6 hours, the eyelid is closed with an anti-allergic adhesive with a width of 1.27. In such a way that one piece of adhesive is placed horizontally on the upper eyelid and the other piece is placed vertically on the patient's eyelid so that it rests on the patient's cheek and eyelid. Examines in terms of damage. If the adhesive needs to be renewed, this will be done. Every 6 hours the patient's eyes will be rinsed with sterile water and cotton and the eye care will be re-applie..Another patient's eye care was performed with artificial tears. That is, every 6 hours the nurse in charge trained by the researcher washes her hands and pours artificial tears into the other eye. For further care of the patient's eyes, the nurse is rinsed with sterile water and cotton, and the procedure is repeated again..Eye care was performed 3 times every 24 hours. Eye care was performed at night.Consumption of.Anti-allergic adhesive with width: 1/27.Company Sins Max and .Sina Darou Tehran Artificial Tears.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi Hospital of Yazd

##### Full name of responsible person

Elham Fazljoo

##### Street address

No. 33, Fifth Lane, Shahid Zineli Alley, Fajr Dahi Boulevard

##### City

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##### Province

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##### Postal code

894946819

##### Phone

+98 35 3624 6804

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+98 35 3235 8700

##### Email

efazljoo@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

DR. Masood Mirzai

**Street address**

No. 33, Fifth Lane, Shahid Zineli Alley, Fajr Dahi Boulevard

**City**

یزد

**Province**

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Efazljoo@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Elham Fazljoo

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Email**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Elham Fazljoo

**Position**

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**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

**Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Elham Fazljoo

**Position**

Faculty Member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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**Email**

Efazljoo@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**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

All data can be published

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

6 months after printing the results

**To whom data/document is available**

Specialists affiliated with medical universities

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

Nurses working in the intensive care unit

**From where data/document is obtainable**

Efazljoo@gmail.com

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

Necessary information on the cause of the need for data information Documentation needed for data

**Comments**