Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The Comparison of Three Methods of Eye Care Using Polyethylene Covers, Artificial Tear Gel and Common Method on Prevention of Dry Eye and Corneal Ulcer in Older People Admitted to Intensive Care Units

Protocol summary

Study aim

The aim of this study is comparison of three methods of eye care using polyethylene covers, artificial tear gel and common method on prevention of dry eye and corneal ulcer in older people admitted to Intensive Care Units (ICU) of hospitals affiliated to Shahid Beheshti University of Medical Sciences in 2020.

Design

Clinical trials with control groups, with parallel groups, one-way blind, randomized, and phase 3 were performed on 99 patients. In this study, the available sampling method will be used by random appointment and the participants in the research will be divided into three groups A, B and C. Intervention methods for random assignment will be placed in dark envelopes and each participant will be assigned an envelope using a random number table.

Settings and conduct

For five days, the eye is examined for dry eye using the Schirmer test and the corneal ulcer using the Fluorescein test by the researcher once in the morning.

Participants/Inclusion and exclusion criteria

patients admitted to ICU aged 60 and over, Glasgow Coma Scale score seven and below seven, no dry eye and corneal ulcer at admission, blink count less than five times per minute, no head and face trauma and incomplete eyelid closure, entered the study and patients who have been hospitalized for the past 24 hours, increased level of consciousness, reversal of blinking reflex and allergic to artificial tear gels, they were removed from the study.

Intervention groups

Group A: Artificial tear gel in the right eye every six hours for five days and in the left eye polyethylene coating and its replacement every 12 hours for five days. Group B: Artificial tear gel in the left eye every six hours for five days and in the right eye polyethylene coating and its replacement every 12 hours for five days. Group C: Both eyes of the patient are cared for in the usual way.

Main outcome variables

Dry eye Corneal ulcer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200711048079N1**
Registration date: **2020-08-01, 1399/05/11**
Registration timing: **prospective**

Last update: **2020-08-01, 1399/05/11**
Update count: **0**

Registration date

2020-08-01, 1399/05/11

Registrant information

Name
Mahsa Tebyanian
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Comparison of Three Methods of Eye Care Using Polyethylene Covers, Artificial Tear Gel and Common Method on Prevention of Dry Eye and Corneal Ulcer in Older People Admitted to Intensive Care Units

Public title
The Comparison of Three Methods of Eye Care Using Polyethylene Covers, Artificial Tear Gel and Common Method on Prevention of Dry Eye and Corneal Ulcer in Older People Admitted to Intensive Care Units
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
They are 60 years old or older. Be hospitalized in the intensive care unit. Have a endotracheal tube and be mechanically ventilated. Have a Glasgow coma scale score of seven or below seven. Their body temperature should be between 36.4 to 37.2 in the morning and 37.2 to 37.8 in the evening using an oral thermometer. Do not have dry eyes at the time of admission using the Schirmer test. Do not have corneal ulcers at the time of admission using the Fluorescein test. Blink less than five times per minute. No head and face trauma. Have no signs of increased intracranial pressure. Have no history of using eye lubricants (before hospitalization). Have no history of eye disease or eye surgery. Have no history of hospitalization in the intensive care unit during the past month. Incomplete closing of the eyelids due to the use of sedatives There are no wounds, eye injuries or eye infections
Exclusion criteria:
Patients whose hospitalization time is more than 24 hours. Patients admitted to the ward with a diagnosis of brain death. Patients whose level of consciousness is increased and they are separated from mechanical ventilation Patients' deaths occur. Patients who are admitted to the intensive care unit for less than five days. Patients who are transferred to other wards during the study. Patients whose blinking reflex returns. Patients who are allergic to artificial tears gel.
Age
From **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the available random sampling method will be used and participants in the study are divided into three groups A, B and C, which group A artificial tear gels in the right eye and in the left eye polyethylene Covers, in Group B, artificial tear gels in the left eye and polyethylene Covers in the right eye and Group C, is the usual method. Intervention methods for random assignment will be placed in dark envelopes and each participant will be assigned an envelope using a random number table. The allocation of the number of study participants to each hospital will be based on the number of annual hospitalizations in the intensive care unit of that center.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the patient's condition, which has a decreased level of consciousness, is under mechanical ventilation, and receives sedatives and muscle relaxants, the patient is not aware of the type of intervention, but to any of the participants' legal guardians if they wish to participate in the project, Explanations about the purpose of the research and ensuring the confidentiality of data information and informed consent will be obtained.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of School of Pharmacy, Nursing and Midwifery, Shahid Beheshti University of Medical
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School of Pharmacy, Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Niayesh Highway Intersection, Valiasr St.
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Approval date
2020-07-26, 1399/05/05
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1399.139

Health conditions studied

1

Description of health condition studied
Dry Eye Syndrome
ICD-10 code
H04.12
ICD-10 code description
Dry eye syndrome

2

Description of health condition studied
Corneal Ulcer
ICD-10 code
H16.0
ICD-10 code description
Corneal ulcer

Primary outcomes

1

Description
Dry eye
Timepoint
The first day of intervention and then daily for five days
Method of measurement
Schirmer Test

2

Description
Corneal Ulcer
Timepoint
The first day of intervention and then daily for five days
Method of measurement
Fluorescein Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group A: Artificial tear gels in the right eye every six hours for five days and in the left eye polyethylene coating and its replacement every 12 hours for five days.
Category
Prevention

2

Description
Intervention group: Group B: Artificial tear gels in the left eye every six hours for five days and in the right eye polyethylene coating and its replacement every 12 hours for five days.
Category
Prevention

3

Description
Intervention group: Group C: Both eyes of the patient are cared for in the usual way, so that both eyes are covered with anti-allergy glue and change the glue every 12 hours for five days.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Medical, Educational and Treatment Center of Imam Hussein Hospital
Full name of responsible person
Ali Darvishpoor Kakhki
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Recruitment center
Name of recruitment center
Medical, Educational and Treatment Center of Ayatollah Taleghani Hospital
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Recruitment center
Name of recruitment center
Shahid Modarres Hospital

Full name of responsible person
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Name of recruitment center
Medical, Educational and Treatment Center of Shahid Dr. Labbafi Nezhad Hospital
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Recruitment center
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Recruitment center
Name of recruitment center
National Research Institute of Tuberculosis and Lung Diseases Dr. Masih Daneshvari Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Amir Mohammad Mortazavian Farsani
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Darvishpoor Kakhki

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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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