Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Eye Care Protocol on the Prevention of Eye Surface Disorders in admitted Patients in ICU

Protocol summary

Study aim
Determination the effect of Eye Care Protocol on the Prevention of Eye Surface Disorders in admitted Patients in ICU

Design
Clinical trial using control and intervention groups and randomized on 70 patients

Settings and conduct
A type of eye care protocol was performed for the patient to determine the incidence of eye complications after using this protocol. Initially, the protocol implementation method was taught to ICU nurses by ophthalmologist and the researcher before the intervention. In the initial examination, the health of cornea in eligible patients was examined using fluorescein staining and schirmer test. The schirmer test was used to check for dry eye

Participants/Inclusion and exclusion criteria
Entry criteria was including the age over 18 years and under 75, level of consciousness less than 8, patients with mechanical ventilation and impaired eyelid reflexes

Intervention groups
. The study looked at the effect of eye care, including keeping the eye closed with adhesive tape in patients whose eyelids were incompletely closed, as well as keeping the eye moist with 0.3% Hypromellos tear drops on superficial eye disorders. The eye disorders were keratitis, conjunctivitis, corneal ulcers and dry eyes. This care was performed on both eyes of the intervention group and compared with both patients' eyes in the control group.

Main outcome variables
use of eye care protocol reduced the incidence of keratitis, conjunctivitis, dry eye and corneal ulcers in patients admitted to special wards.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190522043671N1**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **retrospective**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date
2020-10-18, 1399/07/27

Registrant information

Name
Fariba Mobarez

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-25, 1398/02/05

Expected recruitment end date
2019-12-27, 1398/10/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Eye Care Protocol on the Prevention of Eye Surface Disorders in admitted Patients in ICU

Public title

Effect of Eye Care Protocol on the Prevention of Eye Surface Disorders in admitted Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

level of consciousness less than 8, patients with mechanical ventilation and impaired eyelid reflexes no history of hospitalization in the intensive care unit for a last month no history of eye problems (eye diseases) lack of use the ophthalmic medications such as corticosteroid eye drops no allergy to eye lubricants no eye trauma no symptoms of increased intracranial pressure, health of the corneal surface in the initial examination at least 24 hours after the admitted to the intensive care unit

Exclusion criteria:

return of the blinking reflex during the study period discharge or transfer of the patient from the intensive care unit death of the patient before the end of the study period.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **35**

35 patients in the group intervention and 35 patients in the group control

Randomization (investigator's opinion)

Randomized

Randomization description

The present study was a semi-experimental intervention study (ethical code number IR.AJUMS.REC.1398.314) . Samples were selected from a research community that had entry criteria. They were assigned into 2 intervention and control groups randomly. Random allocation of the type of intervention to the subjects in the study (nurses) was random and by the method of random blocks with block size 4 (using the table related to random replacements). A random list was prepared by a statistician. The type of intervention was assigned to each person who entered the study, according to a random list and the corresponding codes. Entry criteria was including the age over 18 years and under 75, level of consciousness less than 8, patients with mechanical ventilation and impaired eyelid reflexes, no history of hospitalization in the intensive care unit for a last month, no history of eye problems (eye diseases), lack of use the ophthalmic medications such as corticosteroid eye drops, no allergy to eye lubricants, no eye trauma, no symptoms of increased intracranial pressure, health of the corneal surface in the initial examination and at least 24 hours after the admitted to the intensive care unit. Exit criteria were the return of the blinking reflex during the study period, discharge or transfer of the patient from the intensive care unit, and death of the patient before the end of the study period.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Ahvaz Jundishapur University of Medical Sciences

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No19,shahrvand Ave,Bahonar,Ahwaz

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Approval date

2019-04-14, 1398/01/25

Ethics committee reference number

IR.AJUMS.REC.1398.314

Health conditions studied

1

Description of health condition studied

keratitis, conjunctivitis , eye dryness ،corneal ulcer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

keratitis , conjunctivitis, eye dryness and corneal ulcer

Timepoint

Before starting the intervention and after the intervention

Method of measurement

schirmer test, use of fluorescein staining and slit lamp manual

Secondary outcomes

1

Description
keratitis , conjunctivitis , eye dryness and corneal ulcer
Timepoint
Befor the intervention,After the intervention
Method of measurement
schirmer test, use of fluorescein staining and slit lamp manual

Intervention groups

1

Description
. For the eye care protocol in eligible hospitalized patients in the ICU: In the first stage, the position of the eyelids was evaluated and according to the position of the eyelids, patients were divided into three groups and appropriate eye care was performed in each group. 1. The first group consisted of patients with closed eyelids. In this group, one drop of Hypromellose 0.3% was applied to both patients' eyes every 2 hours and continued for 4 hours.2. In the second group, conjunctivitis of the eye was only seen. In this group, in addition to using three drops of Hypromellose 0.3% every 2 hours that lasted for 6 hours, the adhesive tape was also used horizontally across the eye to keep the eyes closed (a piece of adhesive was used horizontally on the upper eyelid and another adhesive used under the lower eyelid and on the skin of the face).3. In the third group, the patient's cornea was exposed. These patients are at higher risk. In this group, three drops of Hypromellose 0.3% were applied every 2 hours (for 8 hours), and the adhesive tape was used horizontally throughout the eye to keep the eyes closed.This eye care was performed for 5 days and the ophthalmologist, without knowing the method of eye care, evaluated the patients before and after the intervention using fluorescein staining, schirmer test and slit lamp in terms of superficial eye disorders. The final evaluation was then performed by an ophthalmologist using a portable slit lamp, as well as the nurses' daily notes, ICU charts, and the occurrence of keratitis and conjunctivitis. The presence of white or yellow spots in the cornea was a sign of keratitis, and a red conjunctiva with tearing and swelling of the eyelids, indicated that conjunctivitis would develop. Patients with superficial eye disorders were treated by an ophthalmologist or ICU physician
Category
N/A

2

Description
Control group: all patients in the control group received a routine eye care every 2 hours (including washing the eyelid and surrounding skin using gas and sterile water).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Deputy of Research and Technology Ahwaz Jundishapur University
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
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Full name of responsible person
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Position
MSc Student of Intensive care nursing, Student Research Committee, Ahvaz Jundishapur University of M

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available