The effect of an eye care protocol on the incidence of ocular surface disorders in patients admitted to intensive care unit.

Protocol summary

Study aim
Determining the Effect of Implementation of Eye Care Protocol on Occurrence of Superficial Eye Disorders in Patients admitted to Intensive Care Units

Design
Clinical trial

Settings and conduct
Data collection included demographic information and severity of eye surface disorders from day 2 to day 7 in intensive care units

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients admitted to intensive care units with a level of consciousness equal to or less than 8 and requiring mechanical ventilation and corneal surface health at initial examination.

Intervention groups
Intervention group (left eye): Use lubricant in the lower conjunctival sac for 1 hour every 4 hours, close the eye, endotracheal suction on one side of the bed, if there is superficial dry eye, eyelid cleaning every 2 hours, Use lubricant and close your eyes Control group (right eye): Rinse eyes with sterile gas impregnated with normal saline per shift

Main outcome variables
Superficial eye disorders (dryness and corneal ulcer)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20140307016870N5
Registration date: 2019-11-13, 1398/08/22
Registration timing: retrospective

Last update: 2019-11-13, 1398/08/22
Update count: 0

Registration date

2019-11-13, 1398/08/22

Registrant information
Name
Khadije Nasiriani
Name of organization / entity
Yazd Shahid Sadoughi University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01
Expected recruitment end date
2019-09-22, 1398/06/31
Actual recruitment start date
2019-03-04, 1397/12/13
Actual recruitment end date
2019-06-21, 1398/03/31
Trial completion date
2019-06-21, 1398/03/31

Scientific title
The effect of an eye care protocol on the incidence of ocular surface disorders in patients admitted to intensive care unit.

Public title
Comparison of an the effect of eye care protocol and routine eye care on superficial eye disorders in ICU patients

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Admitted to intensive care unit Reduce the level of consciousness to a maximum of 8 Corneal surface health at initial examination Requires mechanical ventilation and sedation

**Exclusion criteria:**
Facial and eye trauma in a way that prevents eye care History of Ocular Problems (Ocular Diseases, Eye Infection, Ocular Trauma, Chronic Lagophthalmos, Ocular Drugs and Allergies)

**Age**
From 18 years old to 100 years old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
No information

**Sample size**
Target sample size: 32  
Actual sample size reached: 32

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Other

**Other design features**

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**
Name of ethics committee  
Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

**Street address**
School of Nursing & Midwifery, Buali street, Safaieh, Yazd

**City**
Yazd

**Province**
Yazd

**Postal code**
00983518241755

**Approval date**
2018-05-16, 1397/02/26

**Ethics committee reference number**
ir.ssu.medicine.rec.1397.033

**Health conditions studied**

1

**Description of health condition studied**
Corneal surface disorders

**ICD-10 code**
H16.9

**ICD-10 code description**
Unspecified keratitis

**Primary outcomes**

1

**Description**
Dry eye

**Timepoint**
Daily

**Method of measurement**
With fluorescein tape, according to a grading system

**Secondary outcomes**
empty

**Intervention groups**

1

**Description**
Intervention group (Left eye): Eye for risk factors for superficial disorders (decreased blink reflex, sedative use, mechanical ventilation with PEEP greater than 5, ventilation in chronic condition, conjunctival edema, metabolic, cardiac or renal impairment) Was reviewed and recorded daily. Complete closure of the eyelid (Grade Lagophthalmos: Grade 1: Complete eyelid closure, Grade 2: Contact conjunctiva, Grade 3: Contact cornea) were recorded every eight hours. Measures for grade 1 and 2 Lagophthalmos include: Washing hands before and after the procedure, applying lubricant in the inferior conjunctival sac for 1 hour every 4 hours, closing the eye, suctioning the chip on one side of the bed with eyes closed, and if there is an infection Or blinking from time to time. Symptoms of ocular infection (redness, runny nose, swelling of the eyelids, conjunctivitis, hyperemia, peripheral eyelid crust) were recorded every four hours. Measures include: washing hands before and after the procedure, cleaning the eyelids every 4 hours and every 2 hours in the presence of excessive eye discharge or respiratory infection (cleaning the eyelid with gas and swallowing in one direction from the inside out). Superficial dry eye (opacity or opacity of the eye) was recorded every four hours. Measures include, hand washing before and after the procedure, eye hygiene
cleaning the eyelids every 2 hours (cleaning the eyelid with gas and swapping in one direction from the outside), applying lubricant in the lower conjunctival sac 1 cm. Every 4 hours or so, the eyes were not closed if there was an infection or blink. Superficial ocular abnormalities (corneal opacity, epithelial deficiency, corneal insufficiency, localized white spots) were recorded daily. Measures include: Ophthalmologic consultation, Eye hygiene cleaning of the eyelids every 2 hours (cleaning the eyelid with gas and swapping in one direction from the inside out), applying lubricant in the lower conjunctival sac for 1 hour every 4 hours and closing the eye. Control group (right eye): Eye for risk factors for superficial disorders (reduction of blink reflex, sedative use, mechanical ventilation with PEEP greater than 5, ventilation in chronic condition, conjunctival edema, metabolic, cardiac or renal impairment) Daily recorded and recorded. Complete closure of the eyelid (Grade Lagophthalmos: Grade 1: Complete eyelid closure, Grade 2: Contact conjunctiva, Grade 3: Contact cornea) were recorded every eight hours. Symptoms of ocular infection (redness, runny nose, swelling of the eyelids, conjunctivitis, hyperemia, peripheral eyelid crust) were recorded every four hours. Superficial dry eye (opacity or opacity of the eye) was recorded every four hours. Superficial ocular abnormalities (corneal opacity, epithelial deficiency, corneal insufficiency, localized white spots) were recorded daily. Routine care was performed including washing the eyes with sterile gas impregnated with normal saline every eight hours (once per shift).

Category: Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center: Shahid Rahnemoun Hospital of Yazd
Full name of responsible person: azam pourghaffari lahiji
Street address: Shahid Rahnemoun Hospital, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person
Dr khadijah nasiriani

Street address
In Front of the Infertility Center, Safaieh street, Bu Ali Boulevard

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Email: nasiriani@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice chancellor for research, Yazd University of MedicalSciences

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
azam pourghaffari lahiji
Position
Msn In Critical Care Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

Sharing plan
Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not 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
Title and more details about the data/document
The primary outcome data is shared
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Perform meta-analysis and systematic review
From where data/document is obtainable
Dr khadijeh nasiriani, School of Nursing and Midwifery Yazd: In Front of the Infertility Center: Safaieh street: Bu Ali Boulevard, postal code: 00983518241755, 00989133593437
What processes are involved for a request to access data/document
Send email to Azam Purghafari Lahiji by email: apourghaffarilahiji@gmail.com
Comments