

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

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

Protocol summary

2019-11-13, 1398/08/22

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

Registrant information

Name

Khadije Nasiriani

Name of organization / entity

Yazd Shahid Sadoughi University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1755

Email address

nasiriani@ssu.ac.ir

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

2

Description

Ocular surface disoeder

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

City

yazd

Province

Yazd

Postal code

8913893111

Phone

+98 35 3626 0001

Email

apourghaffarilahiji@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Dr khadijeh nasiriani

Street address

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

City

yazd

Province

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00983518241755

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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

Street address

Yazd University of Medical Sciences, School of Nursing and Midwifery Yazd

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Email

apourghaffarilahiji@gmail.com

Person responsible for scientific 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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Phone

+98 35 1824 1755

Fax**Email**

nasiriani@gmail.com

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

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Khadijeh Nasiriani

Position

PhD in Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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