

# 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

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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

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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**

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## 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

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**Phone**

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**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

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