

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of passive blinking exercises on exposure keratopathy in patients hospitalized in intensive care unit

Protocol summary

Study aim

This is a double blind clinical trial to evaluate the effect of passive blinking exercises on exposure keratopathy in patients hospitalized in intensive care unit

Design

51 anesthetized patients admitted to the intensive department will be selected according Inclusion criteria and using simple sampling and one of the eyes as an intervention group (routine care and passive blinking) and the eye as a control group (routine care alone) Will be taken care. For randomization, in 51 patients, the right eye will be placed in the group A and B with blocking method and The opposite eye will receive the opposite treatment in the right eye.

Settings and conduct

51 anesthetized patients admitted to the intensive department in Arak valiasr haospital will be selected according Inclusion criteria and using simple sampling and one of the eyes as an intervention group (routine care and passive blinking) and the eye as a control group (routine care alone) Will be taken care. In the intervention group, in addition to routine care, the passive blinking by the nurse will be performed with 18 to 20 times for 30 seconds and every 30 minutes. Care will be taken in the left and right eyes simultaneously within a week. All patients will be examined for signs of exposure keratopathy at the beginning of hospitalization. eye examination will be done at the beginning of each day by a person using fluorescein paper and a cobalt filter flashlight, and the results will be recorded immediately. To check keratopathy, an eye specialist will use the scale of corneal changes, In this study, participants and examiners are not aware of the allocation of groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age; Unconscious patients with GCS score less than 10 without blinking reaction; No obvious damage to the face and eyes; No dry eyes before admission, According to companions; No history of eye surgery according to

companions; Do not use eye drops before admission ,Having no keratopathy at the start of the study
Exclusion criteria: discharge or transport from ICU; death; Return of corneal refraction and increased consciousness (GCS score 10 and above). Creating scratches and damage from appliances or other medical errors; Length of stay less than 7 days

Intervention groups

Eye care method in intervention group: 1. Wash hands before eye care. 2. Check daily eyes with fluorescein paper and cobalt filter flashlights. 3. If eyes are closed, two tear drops will be used every four hours. 4. If there is Lagopthalmus, two tear drops every four hours and the use of ophthalmic ointment and Close eyes with glue 5. Cover the eye by pad when suction 6. If there is clear damage (such as white or yellow points on the cornea or redness, swelling and conjunctivitis), be advised to the physician. In addition to care, passive blinking by the nurse will be carried out with 18 to 20 times for 30 seconds and every 30 minutes. Eye care method in control group: 1. Wash hands before eye care. 2. Check daily eyes with fluorescein paper and cobalt filter flashlights. 3. If eyes are closed, two tear drops will be used every four hours. 4. If there is Lagopthalmos , two tear drops every four hours and the use of ophthalmic ointment and Close eyes with glue 5. Cover the eye by pad when suction 6. If there is clear damage (such as white or yellow points on the cornea or redness, swelling and conjunctivitis), be advised to the physician. .

Main outcome variables

Severity of exposure keratopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180107038251N1**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **retrospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Nazanin Amini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3366 1308

Email address

nazaninamini69@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-20, 1395/09/30

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

2016-12-20, 1395/09/30

Actual recruitment end date

2017-07-21, 1396/04/30

Trial completion date

empty

Scientific title

The effect of passive blinking exercises on exposure keratopathy in patients hospitalized in intensive care unit

Public title

"The effect of passive blinking on incidence of exposure keratopathy "

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age; Unconscious patients with GCS score less than 10 without blinking reaction; No obvious damage to the face and eyes; No dry eyes before admission, According to companions; No history of eye surgery according to companions; Do not use eye drops before admission , Having no keratopathy at the start of the study

Exclusion criteria:

discharge or transport from ICU; death; Return of corneal refraction and increased consciousness (GCS score 10 and above); Creating scratches and damage from appliances or other medical errors; Length of stay less than 7 days;

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **51**

More than 1 sample in each individual

Number of samples in each individual: **2**

In the control eye , routine care is performed and in intervention eye, in addition to care, passive blinking by the nurse is performed with 18 to 20 times for 30 seconds and every 30 minutes.

Actual sample size reached: **51**

More than 1 sample in each individual

Actual sample size in each individual: **2**

In the control eye , routine care is performed and in intervention eye, in addition to care, passive blinking by the nurse is performed with 18 to 20 times for 30 seconds and every 30 minutes.

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization, In this method, 51patients placed the right eye in a group A and B blocking method, and the opposite eye received Inverse treatment in the right eye.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, examiners are not aware of the allocation of groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

•Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street,Arak,Iran

City

Arak

Province

Markazi

Postal code

1234

Approval date

2016-11-10, 1395/08/20

Ethics committee reference number

IR.ARAKMU.REC.1395.305

Health conditions studied

1

Description of health condition studied

Exposure keratopathy

ICD-10 code

H15-H22

ICD-10 code description

Disorders of sclera, cornea, iris and ciliary body

Primary outcomes

1

Description

Exposure keratopathy severity

Timepoint

Before the study, every morning to 1 week

Method of measurement

Examination with fluorescein paper, and flashlight with cobalt blue light filter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1. Wash hands before eye care.2. 2. Check daily eyes with fluorescein paper and cobalt filter flashlights.3. If eyes are closed, two tear drops will be used every four hours.4. If there is Lagopthalmus, two tear drops every four hours and the use of ophthalmic ointment and Close eyes with glue5. 5. Cover the eye by pad when suction6. If there is clear damage (such as white or yellow points on the cornea or redness, swelling and conjunctivitis), be advised to the physician.In addition to care, passive blinking by the nurse will be carried out with 18 to 20 times for 30 seconds and every 30 minutes.

Category

Prevention

2

Description

Control group: 1. Wash hands before eye care.2. 2. Check daily eyes with fluorescein paper and cobalt filter flashlights.3. If eyes are closed, two tear drops will be used every four hours.4. If there is Lagopthalmus, two tear drops every four hours and the use of ophthalmic ointment and Close eyes with glue5. 5. Cover the eye by pad when suction6. If there is clear damage (such as white or yellow points on the cornea or redness, swelling and conjunctivitis), be advised to the physician.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Nazanin Amini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mr.Nasri

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Nazanin Amini

Position

MSc in Nursing

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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 total potential data can be shared after unidentifiable people

When the data will become available and for how long

2018

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

I have no conditions

From where data/document is obtainable

Arak University of Medical Sciences, Alamoll Huda Street, Railroad Street Arak, Markazi Province, Iran

What processes are involved for a request to access data/document

Visit to Arak Medical University, Faculty of Paramedicine, Anesthesiology Department, Ms. Amini

Comments