

# 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 hospital 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

#### Street address

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

#### City

Arak

#### Province

Markazi

#### Postal code

1234

#### Phone

+98 86 3417 3507

#### Email

nazaninamini69@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Mr.Nasri

#### Street address

Faculty of Nursing and Midwifery, Arak University of Medical Sciences,Sardasht,Arak,Iran

#### City

Arak

#### Province

Markazi

#### Postal code

1234

#### Phone

+98 86 3417 3505

#### Email

nazaninamini69@yahoo.com

### 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

**Street address**

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

**City**

Arak

**Province**

Markazi

**Postal code**

1234

**Phone**

+98 86 3417 3507

**Email**

nazaninamini69@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Korosh Rezaei

**Position**

MSc in Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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

**City**

Arak

**Province**

Markazi

**Postal code**

1234

**Phone**

+98 86 3417 3524

**Email**

k.rezaei@arakmu.ac.ir

## Person responsible for updating data

### 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

**Street address**

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**Phone**

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**Email**

nazaninamini69@yahoo.com

## 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**