

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparing the effectiveness of simple eye ointment with moisture chamber over the eye and eyelid taping to prevent ocular surface disorders in critically ill patients

#### Protocol summary

##### Summary

Unconscious intensive care unit (ICU) patients who are sedated and paralyzed will have inhibited eye protective mechanisms, subjecting them to increased risk of ocular surface disorder (OSD). OSDs can lead to serious eye complications such as corneal perforation, corneal scarring, or long-term visual deficits. Therefore the aim of this study is to compare the effectiveness of simple eye ointment with moisture chamber over the eye (polyethylene wrap) and eyelid taping to prevent OSDs in critically ill patients. In this study, the eligible patients after an initial examination and rejection of OSDs, randomly allocated into one of three groups of methods are available and each patient's eyes are also randomly receive one of the eye cares. There are three groups in this study that they include, group one: each patient receives both simple eye ointment and tape on eyelid which are allocated at random to either the left or right eye, group two: each patient receives both simple eye ointment and polyethylene cover which are allocated at random to either the left or right eye and group three: each patient receives both simple eye ointment and tape on eyelid which are allocated at random to either the left or right eye. In addition, all participants receive a standard eye-cleansing regime using sterile water and gauze 6 hourly to cleanse the eyelids and surrounding skin. Sample's eyes in terms of incidence and severity of OSDs and severity of chemosis are examined on a daily basis and with a portable slit lamp, according to a grading system.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109225426N3**  
Registration date: **2011-10-24, 1390/08/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-10-24, 1390/08/02

##### Registrant information

###### Name

Mehdi Ahmadinejad

###### Name of organization / entity

Anesthesiology department, Kerman University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 0223 5011

###### Email address

m.ahmadinejad@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kerman Medical University Research Center

##### Expected recruitment start date

2011-09-20, 1390/06/29

##### Expected recruitment end date

2012-05-04, 1391/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effectiveness of simple eye ointment with moisture chamber over the eye and eyelid taping to

prevent ocular surface disorders in critically ill patients

## Public title

Comparing the effectiveness of simple eye ointment with moisture chamber over the eye and eyelid taping to prevent ocular surface disorders in critically ill patients

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: the unconscious patient that had no blink reflex; age over 18 years; patients without orbital or ocular injury; patients that have not a previous admission to ICU within a month of enrolment; Patients without a pre-existing eye condition (history of trauma, eye disease or infection, chronic lagophthalmos, irregular blinking, received eye-care treatment and allergy to eye lubricant), Informed consent for recruitment provide by the patient's immediate relatives Exclusion criteria: positive fluorescein stain at the initial eye assessment

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

clinical trail

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kerman University of Medical Sciences Research Center Ethics Committee

##### Street address

Jahad street, Kerman University of Medical Sciences Research Center

##### City

Kerman

##### Postal code

#### Approval date

2011-09-19, 1390/06/28

## Ethics committee reference number

k/90/275

## Health conditions studied

### 1

#### Description of health condition studied

Corneal surface disorders

#### ICD-10 code

H16.9

#### ICD-10 code description

Keratitis, unspecified

### 2

#### Description of health condition studied

Chemosis

#### ICD-10 code

H11.4

#### ICD-10 code description

) Other conjunctival vascular disorders and cysts,(oedema)

## Primary outcomes

### 1

#### Description

Ocular surface disoeder

#### Timepoint

At baseline and then sample's eyes in terms of incidence and severity of ocular surfac disorders are examined on a daily basis to 7 day after initiate of eye care

#### Method of measurement

With a portable slit lamp, according to a grading system

## Secondary outcomes

### 1

#### Description

Chemosis

#### Timepoint

At baseline and then sample's eyes in terms of incidence and severity of chemosis are examined on a daily basis to 7 day after initiate of eye care

#### Method of measurement

With a portable slit lamp, according to a grading system

## Intervention groups

### 1

#### Description

- The simple eye ointment are apply into the pocket between eyeball and the lower lid of patient eye every 6h, by the patient' nurse.

#### Category

Prevention

## 2

### Description

- The patient' eye receives a piece of polyethylene cover tailors to cover the eye from the eyebrow to the cheekbone. The polyethylene cover adheres to patient's face snugly to form a closed moisture chamber. Adhesive tape was used to secure the edges of the polyethylene cover from seam. The polyethylene cover are changes every 6h.

### Category

Prevention

## 3

### Description

- The patient eye are close with tow piece of tape, one on the upper eyelid and one on the lower eyelid. The tapes change every 6h.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

ICU ward, Shahid Bahonar hospital

##### Full name of responsible person

Mehdi Ahmadinejad

##### Street address

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences Research Center

##### Full name of responsible person

Dr. Malekpour Afshar

##### Street address

Kerman University of Medical Sciences Research Center

##### City

Kerman

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Kerman University of Medical Sciences Research Center

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Kerman University of Medical Sciences

#### Full name of responsible person

Dr Mehdi Ahmadi nejad

#### Position

Assistant professor

#### Other areas of specialty/work

#### Street address

ICU ward, Shahid Bahonar hospital

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mehdia50@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Assistant professor

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*