

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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

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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

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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