

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

A comparative survey of three methods eye care using polyethylene cover, polyethylene cover and eye drop and polyethylene cover and eye ointment, to prevent dry eye and corneal abrasion in ICU patients

Protocol summary

Summary

The aim of study is comparing the effectiveness of three methods of eye care including polyethylene cover, polyethylene cover and eye drop, and polyethylene cover and ointment, in the prevention of dry eye and corneal abrasions in hospitalized patients in Intensive Care Unit at teaching Hospitals of Ilam. In this randomized controlled single blind study the samples consist of 172 patients. Inclusion criteria include absence of dryness and corneal abrasion, being connected to the ventilator and incomplete closure of the eyelids. Exclusion criteria are returning of blinking reflex and extubation. Patients will be randomly assign to one of the three groups including polyethylene cover, cover and eye drop, and cover and eye ointment. In each patient, one eye receives routine interventions, and the other one will receive the intervention. In cover group, polyethylene cover is placed on the eye. In cover and drop group, in addition to covering, a drop is dropped in to the lower eyelid every 8 hours. In cover and ointment group, in addition to covering an ophthalmic ointment is used every 8 hours. Finally, after five days, the both eyes will be examine and compare for dryness and abrasion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506294736N8**
Registration date: **2016-07-02, 1395/04/12**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-07-02, 1395/04/12

Registrant information

Name

Alireza Khatony

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative survey of three methods eye care using polyethylene cover, polyethylene cover and eye drop and polyethylene cover and eye ointment, to prevent dry eye and corneal abrasion in ICU patients

Public title

Evaluation of three methods of eye care in the prevention of ocular surface diseases

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age over 18 years, GCS \leq 8, the absence of trauma to the head and face, the lack of a history of eye disease, absence of eye problems caused by diabetes, no history of hospitalization in the ICU over the past month, tracheal tube, connected to mechanical ventilation, length of stay more than 24 hours in the ICU, closing eyelids partially due to the use of neuromuscular relaxants, the negative result of Schirmer and fluorescein test. Exclusion criteria: Return of blinking reflex, extubation, the death of patient, patient transfer to ward

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **172**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Postal code

Approval date

2016-06-08, 1395/03/19

Ethics committee reference number

177

2

Ethics committee

Name of ethics committee

kermanshah university of medical science

Street address

kermanshah, Azadi square, beheshti blvar

City

kermanshah

Postal code

Approval date

2016-06-08, 1395/03/19

Ethics committee reference number

177

Health conditions studied

1

Description of health condition studied

corneal erosion

ICD-10 code

H 16.0

ICD-10 code description

corneal ulcer

2

Description of health condition studied

dry eye

ICD-10 code

H 04.1

ICD-10 code description

Dry eye syndrom

Primary outcomes

1

Description

dry eye, due to reduced blinking reflex

Timepoint

At the start of intervention and then daily during 5 days

Method of measurement

Schirmer Test

2

Description

Corneal abrasion caused by dry eye

Timepoint

At the start of intervention and then daily during 5 days

Method of measurement

manually slit lamp and fluorescein test

Secondary outcomes

empty

Intervention groups

1

Description

At the group A, a polyethylene coating is used on a daily basis for 5 days.

Category

Prevention

2

Description

In Group B, eye drop and polyethylene coating is used. One Drop is dropped inside of the eyelid every 8 hours. polyethylene coating is then put on the eye. Coverage will be replace on a daily basis or if worn or contaminated.

Category

Prevention

3

Description

In group C, polyethylene coating and ophthalmic ointment are used for 5 days. Ointment is used every 8 hours at a rate of 1 cm inside the lower eyelid. polyethylene coating replaced on a daily basis.

Category

Prevention

4

Description

In the control eye, routine cares such as using of antibiotic ointment, washing skin around the eye using tap water, and taping the eyelid will used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafa Khomeini Hospital

Full name of responsible person

Alireza Khatony

Street address

City

Ilam

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Alireza Khatony

Street address

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Behrooz Hamzeh

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

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

Kermanshah School of Nursing and Midwifery

Full name of responsible person

Alireza Khatony

Position

Faculty Member , PhD in Nursing Education

Other areas of specialty/work

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Person responsible for scientific inquiries

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Postal code**Phone****Fax****Email****Web page address****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