Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of two types of eye care for prevention of corneal dryness and corneal defect in ICU patients

Protocol summary

Summary

The aim of the study is to compare the effect of ointment and tape on prevention of corneal abrasion and dryness in ICU patients in Kashan and Tehran selected hospitals. In this study 90 patients who all are hospitalized in Intensive Care Units for at least 5 days, with Glasgow Coma Scale less than 8 and no blinking response and no history of eye trauma and surgery will randomly allocate to 3 groups. All the patients in ointment and tape group will receive eye care including eye irrigation every 8 hours by a qualified nurse then the tape or ointment will be applied to the eyes. The third group will receive the routine care. The corneal dryness and defect will be studied in the first day of admission and 5 days later by an ophthalmologist. In the fifth day the occurance of corneal drynes and corneal ulcer as the oucome variable will be determined by an ophatlmologist and the groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104186228N1**
Registration date: **2011-08-20, 1390/05/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-08-20, 1390/05/29

Registrant information

Name
Negin Masoudi Alavi
Name of organization / entity
Kashan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 36 1555 0021
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masudialavi_n@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Science

Expected recruitment start date

2011-08-21, 1390/05/30

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of two types of eye care for prevention of corneal dryness and corneal defect in ICU patients

Public title

The prevention of eye problems in ICU patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Hospitalized in ICU for at least 5 days; Glasgow Coma Scale less than 8 in admission; No blinking response, normal shirmer test in admission; age between 20-65. Exclusion criteria: History of diabetes; thyroid and liver diseases; history of eye surgery.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kashan University of Medical Science
Street address
Faculty of Nursing and Midwifery, Kashan University of Medical Science, Ghotb Ravandi Highway, Kashan, Iran
City
Kashan
Postal code
Approval date
2011-07-26, 1390/05/04
Ethics committee reference number
1342/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Corneal ulcer and dryness
ICD-10 code
H16.0
ICD-10 code description
Corneal ulcer

Primary outcomes

1

Description
Corneal ulcer
Timepoint
First day and fifth day
Method of measurement
Flourecent test

2

Description
Corneal dryness
Timepoint
First day and fifth day
Method of measurement
Shirmer test

Secondary outcomes

1

Description
none
Timepoint
none
Method of measurement
none

Intervention groups

1

Description
The patients will recieve the routine eye care in the ward
Category
Prevention

2

Description
Eye irrigation every 8 hours and applying adhesive tape horizentaly to close the eye by nurse.
Category
Prevention

3

Description
Eye irrigation every 8 hours and applying the lubricant eye ointment by nurse.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Dr Negin Masoudi Alavi
Street address
Shahid Beheshti Hospital, Ghotb Ravandi Highway, Kashan, Iran
City
Kashan

2

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Street address
Shariati Hospital, Jalal Al Ahmad Boulvard,Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Science
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Street address
Kashan University of Medical Science, Ghotb Ravandi Highway, Kashan, Iran
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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
Kashan University of Medical Science
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
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Person responsible for updating data

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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