

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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 occurrence of corneal dryness and corneal ulcer as the outcome variable will be determined by an ophthalmologist 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)

Phone

+98 36 1555 0021

Email address

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 horizontally 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 Boulevard, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kashan University of Medical Science

Full name of responsible person

Negin Masoudi Alavi

Street address

Kashan University of Medical Science, Ghotb Ravandi Highway, Kashan, Iran

City

Kashan

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**Name of organization / entity**

Kashan University of Medical Science

Full name of responsible person

Negin Masoudi Alavi

Position

Member of scientific mission

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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