Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the Effectiveness of vitamin A eye oinment with eyelid taping in the prevention of ocular surface disorder in patients hospitalized in intensive care unit

Protocol summary

Summary

The purpose of study is to determine the effect of two eye care methods (humid chamber, vitamin A eye ointment) in prevention from ocular surface disorders. Inclusion criteria: over 18 years old; corneal health in the initial of examination; hospitalized in intensive care unit at least for five days; conscious degree less than 8 according to Glasgow Coma Scale; inexistence of face or eye trauma; inexistence of eye problems history. Exclusion criteria: Existence of chemosis; eye lid position grade difference in the initial of examination; Bell's palsy or hemiplegia; also if patient is capable of blinking for five days; corneal disorder at any stage of the test, recorded and the patient excluded from study continuing. The society of under study: our sample include of patients hospitalized in intensive care unit of emdad sabzevar Hospital. Sample size: First, a small sample of 15 patients selected and then sample size is determined. Intervention require: before each time of intervention, the standard eye care which means irrigation of eye and its surrounding skin with normal saline is done. Each of the eyes of patient randomized will receive one of the eye cares for five days. Thus about two centimeters vitamin A eye ointment is applied on inferior fornix in one eye every 8 hour and the other eye will close with Anti-allergenic surgical adhesive paper KBM . The cover will change every 8 hours. Patients are examined daily for the presence of corneal ulcer, dry eye assess with Schirmer test before and end of time the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110124815N1**

Registration date: **2015-11-15, 1394/08/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-11-15, 1394/08/24

Registrant information

Name

Reza Soltanpoor

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences.

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of vitamin A eye oinment with eyelid taping in the prevention of ocular surface disorder in patients hospitalized in intensive care unit

Public title
Comparing the Effectiveness of vitamin A eye oinment with eyelid taping in the prevention of ocular surface disorder .
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: over 18 years old; corneal health in the initial of examination; hospitalized in intensive care unit at least for three days; conscious degree less than 8 according to Glasgow Coma Scale; inexistence of face or eye trauma; inexistence of eye problems history.
Exclusion criteria: Existence of chemosis, eye lid position grade difference in the initial of examination; Bell’s palsy or hemiplegia; also if patient is capable of blinking for three days; corneal disorder at any stage of the test, recorded and the patient excluded from study continuing
Age
From **18 years** old to **139 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
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
Sabzevar University of Medical Sciences
Street address
University of Medical Sciences, Aasadabadi, Street
City
Sabzevar
Postal code
Approval date
2015-10-07, 1394/07/15
Ethics committee reference number
IR.MEDSAB.REC.1394.80

Health conditions studied

1

Description of health condition studied
Ocular Surface Disorders
ICD-10 code
H16.8
ICD-10 code description
Other Keratitis

Primary outcomes

1

Description
Ocular surface disorders
Timepoint
In 1th to 5th days
Method of measurement
The assessment tool of ocular surface disorders in this study is including Schirmer and Fluorescein tests. Schirmer test is done one time before the initiation and one time at the end of the study. To do the test Schirmer's graded paper will inserted in inferior fornix of lower eyelid at the junction of the middle third and outer third of the eyelid and the eyelid is closed and after five minutes, the height of the paper moist is measured in millimeters. Fluorescein test done daily till five days. Thus after corneal staining with fluorescein, existence of corneal damage assess by using pen light with blue light (cobalt) and 20 diopter lens and the test result is ranking according to Oxford grading scale.

Secondary outcomes

empty

Intervention groups

1

Description
After standard eye care (washing the eye and the skin around the eye with five to 10 cc saline), one of the patient' eye were randomize, every 8 hour, the eyelid is closed by Anti-allergy adhesive tape.
Category
Prevention

2

Description
After standard eye care (washing the eyelids and the skin around the eye with five to 10 cc saline), one of the patient' eye were randomized, every 8 hour, about two centimeters the vitamin A ophthalmic ointment are apply into the inferior fornix by the patient' nurse and the eyelid is closed by hand.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Emdadi Shahid Beheshti Hospital
Full name of responsible person
Reza Soltanpoor
Street address
Razi Street Emdadi Shahid Beheshti Hospital
City
Sabzevar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Dr.Alireza Moslem
Street address
Sabzevar University of Medical Sciences, Asadabadi, Street
City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Reza Soltanpoor
Position
M.S Critical Care Nursing
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