

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Comparing the effectiveness of ophthalmic vitamin A ointment and moisture chamber to prevent ocular surface disorders in critically ill patients

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 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. The society of under study: our sample include of patients hospitalized in intensive care unit of Tabriz Alinasab 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 6 hour and the other eye will cover with polyethylene cover. The cover will change every 12 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: **IRCT201402116318N3**

Registration date: **2014-03-19, 1392/12/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-19, 1392/12/28

Registrant information

Name

Monir Nobahar

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences

Expected recruitment start date

2014-02-21, 1392/12/02

Expected recruitment end date

2014-07-24, 1393/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of ophthalmic vitamin A ointment and moisture chamber to prevent ocular surface disorders in critically ill patients

Public title

Comparing the effectiveness of ophthalmic vitamin A

ointment and moisture chamber to prevent ocular surface disorders in critically ill patients

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

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

Semnan University of Medical Sciences

Street address

Semnan, University of Medical Sciences, Nursing and Paramedical University

City

Semnan

Postal code

3513138111

Approval date

2014-03-04, 1392/12/13

Ethics committee reference number

92/415407

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 randomized receives a piece of thin layer of transparent polyethylene to cover the eye from the eyebrow to the cheek bone every 12 hour. Anti-allergy adhesive tape was used to secure the edges of the polyethylene cover.

Category

Other

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 6 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

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz Alinasab Hospital

Full name of responsible person

Monir Nobahar

Street addressSemnan, University of Medical Sciences, Nursing and
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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Dr.Raheb Ghorbani

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Semnan, Bolvar Basij, University of Medical Sciences

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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

Semnan 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**

Semnan University of Medical Sciences

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Position

Dr

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty