

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of ocular lubratex and ocular vitamin A ointment in the prevention of ocular surface disorders (OSD) in Intensive Care Unit, A Randomized Clinical Trial

Protocol summary

2017-07-25, 1396/05/03

Summary

This study aimed to determine the efficacy of eye care (eye ointments Lubratex and topical vitamin A) in the prevention of ocular surface disorders. Inclusion criteria: Age over 18 years; the healthy cornea in the initial examination; admitted to the intensive care unit for at least for 5 days; consciousness score according to the Glasgow Coma Scale less than 10; lack of trauma to the face or eyes; no history of eye problems. Exclusion criteria: having chemosis; differences of scores in the preliminary examination of the eyelid position; Bell's palsy or unilateral hemiplegia; allergy to Lubratex; closed suction method; if the patient is able to blink; corneal disorder at any stage of the testing. Study population: patients who admitted in the intensive care units of (Imam Hossein and Bahar hospitals) in Shahroud. Sample size: 71 patients The required intervention: Before each intervention, standard eye care including eyes cleaning and the skin around it is done with normal saline. Each patient's eye randomly assigned to receive one eye care for five days. So that, every six hours about two inches of vitamin A ointment is used in the lower fornix and in the other eye Lubratex ointment is used. Patients on the first and fifth days are examined by using Schirmer's and fluorescein tests for corneal ulcer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040733278N1**

Registration date: **2017-07-25, 1396/05/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Mitra Badparva

Name of organization / entity

Shahroud University of Medical Sciences

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Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2017-06-10, 1396/03/20

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ocular lubratex and ocular vitamin A ointment in the prevention of ocular surface disorders (OSD) in Intensive Care Unit, A Randomized Clinical Trial

Public title

Effect of eye ointmet lubratex in the prevetion ocular surface disorders (OSD)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age over 18 years; the healthy cornea in the initial examination; admitted to the intensive care unit for at least for 5 days; consciousness score according to the Glasgow Coma Scale less than 10; lack of trauma to the face or eyes; no history of eye problems. Exclusion criteria: having chemosis; differences of scores in the preliminary examination of the eyelid position; Bell's palsy or unilateral hemiplegia; allergy to Lubratex; closed suction method; if the patient is able to blink; corneal disorder at any stage of the testing.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **71**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

Shahroud- 7th Tir square

City

Shahroud

Postal code

3614773955

Approval date

2017-05-28, 1396/03/07

Ethics committee reference number

ir.shmu.rec.1396.18

Health conditions studied

1

Description of health condition studied

Ocular Surface Disorders

ICD-10 code

H19-H22

ICD-10 code description

Disorders of sclera, cornea, iris and ciliary body

Primary outcomes

1

Description

Ocular Surface Disorders

Timepoint

Before intervention- 5 days after the intervention.

Method of measurement

Assessment tools for ocular surface disorders in this study including the Schirmer's and fluorescein tests. Schirmer's test once before and once when the study is completed will be done. To perform this test graded Schirmer's paper is placed in choledosac at the junction of the middle third and outer third of the eyelid and the lid is closed. After five minutes, wet bar's height is measured in millimeters. Fluorescein test once at the beginning and once on the fifth day is done.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After a standard eye care (eye wash and skin around it with normal saline) one of the eyes of patients is randomly selected. Then about two inches Lubratex Ointment every six hours, 5 days, is placed in lower eye fornix by the charge nurse and eyelids will be closed by hand. Patients on the first and fifth days are examined by using Schirmer's and fluorescein tests for corneal ulcer.

Category

Prevention

2

Description

Control group: After a standard eye care (eye wash and skin around it with normal saline) other patient's eye is selected. Then about two inches vitamin A Ointment every six hours, 5 days, is placed in lower eye fornix by the charge nurse and eyelids will be closed by hand. Patients on the first and fifth days are examined by using Schirmer's and fluorescein tests for corneal ulcer.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Dr Mohammad Veshagh (An ophthalmologist)

Street address

Imam' Street, Imam Hossein Square

City

Shahroud

2

Recruitment center

Name of recruitment center

Bahar Hospital

Full name of responsible person

Dr Mohammad Veshagh (Ophthalmologist)

Street address

22 Bahman' Street

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Department of Technology and Research of Shahroud
University of Medical Sciences

Full name of responsible person

Dr: Mohammad Hassan emamian

Street address

University of Medical Sciences, 7th Tir square

City

Shahroud

Grant name

دانشگاه علوم پزشکی شاهرود

Grant code / Reference number

دانشگاه علوم پزشکی شاهرود

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

Yes

Title of funding source

Department of Technology and Research of Shahroud
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

Shahroud University of Medical Sciences

Full name of responsible person

Mitra Badparva

Position

Nursing Graduate Student

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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