

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 5054

##### Email address

badparva@shmu.ac.ir

#### 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

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*