# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**
Semnan University of Medical Sciences
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Iran (Islamic Republic of)
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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 address**
Semnan, University of Medical Sciences, Nursing and Paramedical University
**City**
Semnan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Dr.Raheb Ghorbani
**Street address**
Semnan, Bolvar Basij, University of Medical Sciences
**City**
Semnan
**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

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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*