

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparing the Effectiveness of vitamin A eye ointment 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

Sabzevar University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 1656

Email address

soltanpoorr1@medsab.ac.ir

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 ointment 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 ointment 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

Street address

Sabzevar University of Medical Sciences School
Nursing and Midwifery

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

soltanpoorr1@medsab.ac.irrsoltanpoor256@gmail.co
m

Web page address

Person responsible for scientific 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

Street address

Sabzevar University of Medical Sciences -School of
Nursing and Midwifery

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

soltanpoorr1@medsab.ac.ir

Web page address

Person responsible for updating data

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

Street address

Sabzevar University of Medical Sciences -School of
Nursing and Midwifery

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

soltanpoorr1@medsab.ac.irrsoltanpoor256@gmail.co
m

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