Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Effect of the eye care protocol on ocular damage in patients hospitalized in intensive care unit

Protocol summary

Study aim

this study was to identify the effect of an eye care program on the number of eye injuries in hospitalized patients in intensive care units

Design

This research is a clinical trial, conducted on 70 ICU patients who were selected by convenient sampling by random number boxes and assigned study (n=35) and control(n=35) groups by random allocation.

Settings and conduct

This study is hospitalized patients in intensive care units.One group received routine eye care (control group) and the other (test group) received eye care program(cleaning the eye every 8 hours and using simple eye ointment in eye ,closing the eyelid with tape and putting a wet pad on the eyes

Participants/Inclusion and exclusion criteria

Inclusion criteria were patients over 18 years of age with over 24 h on ventilator and GCS of less than 7. In cases of patients death, discharge or transition from ICU, increase in level of consciousness the patient is excluded.

Intervention groups

In control group, routine care including cleaning patients' eyelids with a normal saline gauze. In study group, eyes are cleaning by a normal saline gauze while eyes closed and were dressed by eye ointments used in the lower sack of patients' eye. Then, patients' eyes are fixing by anti allergic transparent tape and covered by a normal saline gauze completely. This care is administrated during each working shift for 7 days for two groups. The patients are assessing concerning corneal injury with fluorescent test once a day in both groups if the patient showed a sign of corneal injury (positive fluorescent test) within 7 days undergoing assessment, and he ordered counseling with an ophthalmologist not only to diagnose the eye injury and its type but also to start relevant treatment .

Main outcome variables

using an eye care program, while taking care of hospitalized patients in intensive care unit is recommended to be an effective method in the prevention of ocular surface disorder.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160101025787N1**
Registration date: **2017-12-30, 1396/10/09**
Registration timing: **retrospective**

Last update: **2017-12-30, 1396/10/09**
Update count: **0**

Registration date

2017-12-30, 1396/10/09

Registrant information

Name

Fouziyeh Mokhtari

Name of organization / entity

School of Nursing and Midwifery, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7540

Email address

f.mokhtari1391@yahoo.com

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the eye care protocol on ocular damage in patients hospitalized in intensive care unit

Public title

eye care program

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

patients over 18 years of age over 24hrs on ventilator GCS of less than 7(without consideration of T score) lack of eye blinks reflex disability of keeping eyes closed no ocular injury in fluorescent test no head traumas

Exclusion criteria:

patients death discharge or transition from ICU loss of patient’s family’s interest to stay in study increase in level of consciousness or return of eye blinks reflex

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Firstly, subjects are selected through convenient sampling, and then, assigned to study and control groups through random allocation and with help of random numbers and case numbers, given to the subjects . It was so that the first number , taken out of the box , defines the subject to be given to control, and the next, the one given to the study group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, hezar-jarib street, Isfahan .

City

Isfahan

Province

Isfehan

Postal code

۸۱۷۴۶-۷۳۴۶۱

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

393242

Health conditions studied

1

Description of health condition studied

Ocular Surface Disorder

ICD-10 code

H16.0

ICD-10 code description

Corneal ulcer

Primary outcomes

1

Description

eye disorder

Timepoint

Daily for seven sequential days

Method of measurement

With Fluorescent test

Secondary outcomes

empty

Intervention groups

1

Description

In study group, while the eye lids are closed and are cleaned with normal saline gauze, eye ointment (loubratex containing white paraffin, lanolin and liquid paraffin, made by Sina Daroo company) is dropped into the lower eye sack of the patients, and then, the eye lids are closed and fixed by two anti-allergic transparent adherent tapes (horizontally laid on the lower and upper eye lids). Normal saline sterile gauze is laid on patients’ eyes so as to cover the eyes completely. Then, these procedures are repeated in each working shift by the researcher and the nurse. In each shift, the assessment

of the return of the patients' blinking reflex is done by the nurse or the researcher during the implementation of the care plan on their eyes.

Category

Prevention

2

Description

In control group, assessment of patients' blinking reflex and GCS is implemented by a trained nurse and the researcher. Patients also receive routine eye care, administrated in the ward, including cleaning the patients' eye lids with saline normal gauze.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al- Zahra Hospital

Full name of responsible person

Parviz Kashefi, Anesthesiologist

Street address

Isfahan, Shahid Keshari Highway, Sofh Boulevard , Al-Zahra Educational Center.

City

Isfahan

Province

Isfehan

Postal code

۸۱۷۴۶-۷۳۴۶۱

Phone

+98 31 3668 0048

Email

f.mokhtari1391@ahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedean Atar

Street address

Isfahan, sfahan University of Medical Sciences,Research Center

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

f.mokhtari1391@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Fouziyeh Mokhtari

Position

Master of Critical Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Dormitory complex of Medical Sciences, Isfahan Univercity of Medical Sciences, Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 913 729 8994

Fax

Email

f.mokhtari1391@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences

Full name of responsible person

AhmadReza Yazdannik

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Isfahan University of Medical Sciences, Isfahan

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3729 7540

Fax

Email

Yazdannik@nm.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences

Full name of responsible person

Fouziyeh Mokhtari

Position

Master of Critical Care Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Dormitory complex of Medical Sciences,Isfahan Univercity of Medical Sciences,Isfahan, Iran.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 7540

Fax

Email

f.mokhtari1391@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Total potential data after unidentifiable individuals

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Researchers in academic and scientific institutions

Under which criteria data/document could be used

Data can be used for scientific and research studies.

From where data/document is obtainable

call Fouziyeh Mokhtari via f.mokhtari1391@yahoo.com, fouziyeh.mokhtari@hums.ac.ir , Telephone: 00989137298994

What processes are involved for a request to access data/document

After receiving the request email, data files will be sent in less than a week.

Comments