Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the Effect of Polyurethane cover and eyelid massage on the Prevention of Keratopathy in Intensive Care Unit Patients

Protocol summary

Study aim
prevention of keratopathy
Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment
Settings and conduct
ICU Therma and General Divisions of Ninth Day Hospital and Razi Hospital of Torbat Heydariyeh Interventions include the use of polyurethane coating or right eyelid massage in the left eye in both control groups.
Participants/Inclusion and exclusion criteria
Admitted to the intensive care unit, Score less than 8 according to Glasgow criteria, Lack of history of liver, diabetes, thyroid and ocular diseases, Negative Fluorescein and schirmere test at admission, Absence of eye trauma.
Intervention groups
1 Polyurethane coating on right eye of group I 2 Inactive Movement on Right Eye of Group II 3 The left eyes are both control groups
Main outcome variables
Lagophthalmos / Mechanical Ventilation / Muscle Relaxants / sedatives / Level of Consciousness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200106046032N1**
Registration date: **2020-03-17, 1398/12/27**
Registration timing: **retrospective**

Last update: **2020-03-17, 1398/12/27**
Update count: **0**
Registration date
2020-03-17, 1398/12/27

Registrant information
Name
fahimeh masoudi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5231 7001
Email address
farimehrmasoudi@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-05-05, 1398/02/15
Expected recruitment end date
2019-10-07, 1398/07/15
Actual recruitment start date
2019-05-05, 1398/02/15
Actual recruitment end date
2020-01-02, 1398/10/12
Trial completion date
2020-01-20, 1398/10/30

Scientific title
Comparison the Effect of Polyurethane cover and eyelid massage on the Prevention of Keratopathy in Intensive Care Unit Patients

Public title
Effect of polyurethane coating on corneal scratch prevention, effect of inactive lid movement on corneal scratch prevention
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being in the intensive care unit Conscientiousness score less than 8 according to Glasgow criteria No history of liver, diabetes, thyroid and ocular diseases Age 15-15

years Absence of eye trauma Negative Schirmer and Fluorescein test at admission

Exclusion criteria:

1.Eye trauma while studying Relapse reflex of blinking patient Patient discharge before intervention Unwillingness of the patient's family to continue the study The current clinical conditions that limit the intervention

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

The patient's right eye is in the intervention group and his left eye is in the control group

Actual sample size reached: **60**

More than 1 sample in each individual

Actual sample size in each individual: **2**

The patient's right eye is in the intervention group and his left eye is in the control group

Randomization (investigator's opinion)

Randomized

Randomization description

The research sample was selected based on the inclusion criteria and then randomly assigned to two groups of polyurethane coating and passive eyelid motion using random number table. Six possible modes (BBAA, AABB, ABAB, BABA, ABBA, BAAB) are listed and randomly the number of blocks required is specified and the clients are ranked accordingly.They were divided into two groups: polyurethane coating (A) and inactive lid movement (B). In each group, right eye was considered as intervention and left eye as control.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients have decreased consciousness. The outcome assessor (eye specialist) is not aware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی گناباد

Street address

mansoorieh 9 AVE

City

تربت حیدریه

Province

Razavi Khorasan

Postal code

9518954746

Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.GMU.REC.1398.052

Health conditions studied

1

Description of health condition studied

exposure keratopathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blink Disorder

Timepoint

daily

Method of measurement

Observation and examination

Secondary outcomes

1

Description

Scratches and corneal ulcers

Timepoint

daily

Method of measurement

Fluorescein testing and use of cobalt blue light

Intervention groups

1

Description

Intervention group : Using polyurethane coating Askinaderm: In this study, polyurethane coating is used to create a moist chamber on the eye that restricts tear evaporation. Its dimensions range from eyebrows to cheek bumps and from the nasal bridge to one centimeter beyond the outer corner of the eye in such a way that it turns the eye rim into a closed chamber. This cover is replaced daily.

Category
Prevention

2

Description
Intervention group: Massage the eyelids: Passive movement of the eyelid, massage the eyelid, or moving the eyelid gently from the root to its periphery, or the gentle pressure of the eyelids up or down, and the lateral movement from the inner corner of the eye to the outer corner. Passive movement of the patient's eyelids is performed by the nurse three times a day for 5 minutes.
Category
Prevention

3

Description
Control group: Routine care: Rinse with normal saline and close with regular glue
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان های رازی و نهم دی
Full name of responsible person
فهیمه مسعودی
Street address
mansoorieh 9 AVE
City
Torbat e heydarieh
Province
Razavi Khorasan
Postal code
9518954746
Phone
+98 51 5231 7001
Email
farimehrmasoudi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
moosa Sajjadi
Street address
Beginning of the Qaen Belt Road
City
Gonabad
Province
Razavi Khorasan
Postal code
9691797852
Phone
+98 51 5722 5813
Email
info@gmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad University of Medical Sciences
Proportion provided by this source
40
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
Gonabad University of Medical Sciences
Full name of responsible person
FAHIMEH MASOUDI
Position
NURSE
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
MANSOORIEH 9
City
TORBAT E HEYDARIEH
Province
Razavi Khorasan
Postal code
9518954746
Phone
+98 51 5231 7001
Email
farimehrmasoudi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Fahimeh Masoudi
Position
Head nurse
Latest degree
Bachelor

Other areas of specialty/work
Nursery
Street address
Mansoorieh 9 Ave
City
Torbat e heydarieh
Province
Razavi Khorasan
Postal code
9518954746
Phone
+98 51 5231 7001
Email
farimehrmasoudi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Fahimeh masoudi
Position
Head Nurse
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Mansoorieh 9 Ave
City
Torbat e heydarieh
Province
Razavi Khorasan
Postal code
9518954746
Phone
+98 51 5231 7001
Email
farimehrmasoudi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available