Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Balanced Salt Solution on Dry eye in Hospitalized Comatose Patients in Intensive care units

Protocol summary

Study aim
The effect of "Balanced Salt Solution" on dry eye will be evaluated in hospitalized patients in intensive care units

Design
40 anesthetized patients admitted to the intensive care unit will be selected according inclusion criteria and using non-probability sampling .One eye will be cared as intervention group (BSS care) and the other eye as control (artificial tear care) .For randomization,coin toss will be used to allocate each eye to two treatments(simple random allocation).One eye assigned to the intervention group and the other to the control group

Settings and conduct
This study will be performed on patients admitted to intensive care unit of Shohada-ye Ashayer Hospital of Khorramabad.The artificial tear control group and the intervention group will receive a formulated eye care program (BSS)

Participants/Inclusion and exclusion criteria
Inclusion criteria:Patients 18-75 years;Over 24 h on ventilator and GCS of less than 10 and no blinking reaction;No trauma to the face and eyes;Stay in ICU ward for at least 5 days;Not having a known history of ophthalmic disease;and ophthalmic surgery in the last 6 months.Exclusion criteria:Discharge from ICU; Death; Corneal reflex return and GCS score of 10 and above; Hospital stay less than 5 day

Intervention groups
At the beginning of the study,Schirmer test and Tear Breakup Time (TBUT) will be performed.Then each patient's eyes will be cared for 5 days using one of the eye solutions (BSS and artificial tears).Care protocol in control group including hand washing before eye care and use of artificial tears every 6 hours (2 drops) also, sterile eye ointment and adhesive tape will be used on the eyes.In the intervention group, in Addition to the routine care protocol (hand washing, eye ointment and adhesive tape), BSS drops will be used every 6 hours (2 drops) for the patient's eye

Main outcome variables
Dry eye

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200113046121N1**
Registration date: **2020-02-18, 1398/11/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-18, 1398/11/29**
Update count: **0**

Registration date
2020-02-18, 1398/11/29

Registrant information

Name
parastou kordestani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3323 3040

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kordestani.p@lums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Balanced Salt Solution on Dry eye in Hospitalized Comatose Patients in Intensive care units

Public title

Effect of Balanced Salt Solution on Dry eye

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients admitted to the ICU ward with supportive mechanical ventilation admitted within the first 24 hours 18-75 years old No known history of ophthalmic,Liver, Diabetes, Thyroid And Ocular surgery in the last 6 months No history of systemic disease such as Sjogren's syndrome, progressive Sclerosis, Sarcoidosis, Leukemia, Lymphoma At baseline GCS study <10 Patients whose cause is not facial and eye trauma. Patients who have been in the ICU ward for at least 5 days

Exclusion criteria:

Patients with a hospital Stay of less than 5 days for any reason (Death, Discharge, Transfer) If the patient's GCS reaches above 10 within the first three days of admission Patients with altered consciousness may cause blinking on their own

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups: Coin toss will be used to allocate each eye to two treatments (simple random allocation), with one eye assigned to the case group and the other to the control group

Blinding (investigator's opinion)

Triple blinded

Blinding description

Clinical care nurses will not be aware of the type of solution used (label A, B will be available on both solutions) The optometrist will be unaware of the type of care The data analyzer will also be unaware of the type of care

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences Khoramabad, Lorestan, Iran

City

khorramabad

Province

Lorestan

Postal code

381351698

Approval date

2019-04-15, 1398/01/26

Ethics committee reference number

IR.LUMS.REC.1398.025

Health conditions studied

1

Description of health condition studied

dry eye

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dry eye severity

Timepoint

The first day of hospitalization and the fifth day

Method of measurement

1-Schirmer test 2-Tear Breakup Time with cobalt blue light filter ophtalmoscop

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:1-Schimmer test and TBUT for Dry eye examination before intervention by an optometrist 2-Wash hands before eye care 3-Applying a Balanced Salt

Solution every 6 hours (2 drops) will also be followed by sterile eye ointment and adhesive tape on the eye

Category

Prevention

2

Description

Control group: 1-Schimmer test and TBUT for Dry eye examination before intervention by an optometrist 2-Wash hands before eye care 3-Applying a artificial tears every 6 hours (2 drops) will also be followed by sterile eye ointment and adhesive tape on the eye

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-ye Ashayer Khorramabd Hospital

Full name of responsible person

Hengameh Sadeghi Hasanvand

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences Khoramabad, Lorestan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Ebrahim Falahi

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falahi.e@lums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

student

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Hengameh Sadeghi Hasanvand

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Parastou Kordestani Moghadam

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
Nursery
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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