

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Effect of autologous serum drop on the occurrence of exposure keratopathy in patients hospitalized intensive care units

Protocol summary

Study aim

Effect of autologous serum drop on the occurrence of exposure keratopathy in patients hospitalized in intensive care units

Design

Non blinded parallel randomized clinical trials with control group

Settings and conduct

The present study is a clinical trial will be perform in the intensive care unit of Vali-e-Asr Hospital in Arak. Patients are selected using targeted sampling and are included in the study, and one of the eyes is cared by the "A" and the other by "B" methods.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalization in intensive care unit 16 - 65 years old Signing the consent form Awareness score less than 10 according to Glasgow Coma Scale No history of eye disease before hospitalization Non-traumatic face and eye No history of consumption of ointment and ocular drops before hospitalization Exclusion criteria: Unwillingness to participating in the study

Intervention groups

One of the eyes is cared with "A" and the other with "B" methods. Coin throwing is done to determine the care method in each eye. In other words, "A" care method is considered as a control group and the "B" care method as an intervention group. "A" care method includes: Wash hands before eye care - Eye wash with sterile sterile technique, every 6 hours - use of artificial tear drops every six hours - covering the eye with the pad at the time of suction. In the "B" care method, in addition to the above actions, two drops of autologous serum drops are used every six hours.

Main outcome variables

Exposure keratopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161210031328N9**
Registration date: **2019-04-10, 1398/01/21**
Registration timing: **retrospective**

Last update: **2019-04-10, 1398/01/21**

Update count: **0**

Registration date

2019-04-10, 1398/01/21

Registrant information

Name

Mahbobeh Sajadi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3402 0115

Email address

m.sajadi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-11, 1397/09/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of autologous serum drop on the occurrence of exposure keratopathy in patients hospitalized intensive

care units

Public title

The effect of autologous serum drops on keratopathy in patients hospitalized in intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization in intensive care unit 16 - 65 years old
Signing the consent form Awareness score less than 10 according to Glasgow Coma Scale No history of eye disease before hospitalization Non-traumatic face and eye No history of consumption of ointment and ocular drops before hospitalization

Exclusion criteria:

Unwillingness to participating in the study

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

One of the eyes is cared with "A" and the other with "B" care methods. Coin throwing is done to determine the care method in each eye. Therefore, in some patients, the left eye, and in some patients, the right eye is cared with the "B" method, and so the "A" care is done both in the right eye and in the left eye of the patients. In other words, care "A" care method is considered as a control group and a "B" care method as an intervention 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 Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Sq., Sardasht Region

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.ARAKMU.REC.1397.291

Health conditions studied

1

Description of health condition studied

Keratopathy

ICD-10 code

H18.9

ICD-10 code description

Unspecified disorder of cornea

Primary outcomes

1

Description

Exposure keratopathy

Timepoint

Examination of the eye before study, using fluorescein paper and ophthalmoscope with blue cobalt light filter, and then daily and at the beginning of each day.

Method of measurement

The scale of corneal changes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The right eye will be considered as intervention group. In addition to routine care, autologous serum drops are cast in the right eye every six hours. In order to provide an autologous serum, 10 to 20 ml of blood will be taken from the patient and according to the standard protocol in the laboratory of Valiasr Hospital in Arak, six sterile drops are prepared.

Category

Prevention

2

Description

Control group: The left eye of patients will be considered as control group. In this group, routine care will be done on the eye.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-asr Hospital

Full name of responsible person

Seyed Mohammad Jamalian

Street address

Vali-e-asr Hospital, Vali-e-asr sq.

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3814957558

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pr_valieasr@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

Street address

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info@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mahbobeh Sajadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Sina Dehghan

Position

MSc. Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information on the main outcome and the demographic information, can be shared.

When the data will become available and for how long

36 months after publishing of results.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

In order to utilize scientific purposes and mention the source used.

From where data/document is obtainable

Dr. Mahboubeh Sajjadi E-mail address:
sajadimahbobeh@yahoo.com

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

After receiving the email, the information will be sent within 2 to 3 working days.

Comments