

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of polyethylene film and artificial tear versus normal saline on the incidence of superficial ocular disorders in unconscious patients: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of polyethylene film and artificial tear versus normal saline on the incidence of superficial ocular disorders in unconscious patients.

Design: a triple blind randomized clinical trial. **Setting and conduct:** The eligible unconscious patients who are hospitalized in ICU ward of Besat Hospital will be enrolled into the trial. **Inclusion criteria:** age of 18 to 80 years; conscious level of 8 or lower based on GCS scale; healthy cornea; lack of blinking reflex. **Exclusion criteria:** head trauma; history of cataract surgery; history of glaucoma; increasing the conscious level above 8 based on GCS scale; backing the blinking reflex; need to cardiopulmonary resuscitation. **Intervention group 1:** Covering the eye with polyethylene film and replacing it every 12 hours for 5 days. **Intervention group 2:** Dropping 2 drops of artificial tear every 6 hours for 5 days. **Control group:** Irrigation of eye with normal saline every 6 hours for 5 days. **Primary outcome:** Assessing the superficial ocular disorders on first and fifth days through physical examination. **Secondary outcome:** Nothing. **Randomization:** The patients will be randomly assigned to intervention and control groups using block randomization. **Blinding:** Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609129014N115**
Registration date: **2016-09-21, 1395/06/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-09-21, 1395/06/31

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of polyethylene film and artificial tear versus normal saline on the incidence of superficial ocular disorders in unconscious patients: a triple blind randomized clinical trial

Public title

Effect of polyethylene film and artificial tear versus normal saline on the incidence of superficial ocular disorders in unconscious patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 18 to 80 years; conscious level of 8 or lower based on GCS scale; healthy cornea; lack of blinking reflex. Exclusion criteria: head trauma; history of cataract surgery; history of glaucoma; increasing the conscious level above 8 based on GCS scale; backing the blinking reflex; need to cardiopulmonary resuscitation.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2016-08-27, 1395/06/06

Ethics committee reference number

IR.UMSHA.REC.1395.262

Health conditions studied**1****Description of health condition studied**

unconscious patients

ICD-10 code

R40.2

ICD-10 code description

Coma, unspecified

Primary outcomes**1****Description**

Assessing the superficial ocular disorders

Timepoint

on the first and fifth days

Method of measurement

through physical examination

Secondary outcomes**1****Description**

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups**1****Description**

Covering the eye with polyethylene film and replacing it every 12 hours for 5 days

Category

Prevention

2**Description**

Dropping 2 drops of artificial tear every 6 hours for 5 days

Category

Prevention

3**Description**

Irrigation of eye with normal saline every 6 hours for 5 days

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Hamid Moradi Amin

Street address

Besat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences**Full name of responsible person**

Dr Saeid Bashirian

Street addressHamadan University of Medical Sciences, Shahid
Fahmideh Ave**City**

Hamadan

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

Yes

Title of funding sourceVice-chancellor for Research the Technology, Hamadan
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**

Besat Hospital

Full name of responsible person

Hamid Moradi Amin

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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