Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparing the effect of vitamin A ointment and Liposic gel for prevention of corneal abrasion during general anesthesia in nonocular surgeries

Protocol summary

Study aim
Comparing the effect of vitamin A ointment and Liposic gel for prevention of corneal abrasion during general anesthesia in nonocular surgeries

Design
parallel group blinded randomized trial on 50 patients

Settings and conduct
Sampling is performed in the operating room of hospitals affiliated to Arak University of Medical Sciences. Intervention group 1 (Vitamin A ointment) and intervention 2(Liposic gel) are assigned. As soon as the study was completed, demographic information is recorded . The eyes are examined for corneal damage before anesthesia, immediately after anesthesia, and 24 hours later. All assessments are performed by a researcher trained by an ophthalmologist who is unaware of the classification. Fluorescein paper and a flashlight with a cobalt blue light filter are used to assess corneal damage. 24 hours after surgery patient's eye discomfort questionnaire by patient is completed. patient is unaware of the assignment of groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients older than 18 years and less than 75 years; Patients undergoing non-ocular surgery with general anesthesia; No obvious damage to face and eyes; Lack of recent hospitalization in intensive care unit; No eye diseases (keratitis, keratopathy, glaucoma and other eye diseases); American Society Of Anesthesiologist Physical status I and II; Duration of surgery between 60-300 minutes; Supine position during surgery Exclusion criteria: Head and neck surgery; Need for invasive interventions and hospitalization in intensive care units; End of surgery before 60 minutes

Intervention groups
As soon as anesthesia and blinking reflex disappear in the first group eye care is given with vitamin A and in second group eye care is given with Liposic eye gel

Main outcome variables
Corneal abrasion Ophthalmic discomfort

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180107038251N4**
Registration date: **2020-10-14, 1399/07/23**
Registration timing: **prospective**

Last update: **2020-10-14, 1399/07/23**
Update count: **0**

Registration date
2020-10-14, 1399/07/23

Registrant information

Name
Nazanin Amini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3366 1308

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of vitamin A ointment and Liposic gel for prevention of corneal abrasion during general anesthesia in nonocular surgeries

Public title
Comparing the effect of vitamin A ointment and Liposic gel for prevention of corneal abrasion
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 18 years and less than 75 years Patients undergoing non-ocular surgery with general anesthesia No obvious damage to face and eyes Lack of recent hospitalization in intensive care unit No eye damage before surgery according to the patient No eye diseases (keratitis, keratopathy, glaucoma and other eye diseases) American Society Of Anesthesiologist Physical status I and II Patients with endotracheal intubation Duration of surgery between 60-300 minutes Supine position during surgery No allergy to fluorescein No pregnancy Negative preoperative fluorescein staining No severe systemic diseases Do not use drugs that affect the production of tears in a recent month
Exclusion criteria:
Head and neck surgery Death during surgery Lack of patient cooperation and inability to answer questions related to ocular symptoms after surgery Need for invasive interventions and hospitalization in intensive care units End of surgery before 60 minutes
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patient's two eyes are divided into two groups of intervention 1 and intervention 2 using simple random sampling method. 25 envelopes containing the letters A (right eye of vitamin A ointment and left eye of Liposic gel) and envelopes containing the letters B (right eye of Liposic gel and left eye of vitamin A ointment) are prepared. With this method, the right eye of half of patients is placed in the group of vitamin A ointment and the right eye of half of the patients is placed in the group of Liposic gel and vice versa.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients and examiners are not aware of the allocation of groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Railroad Street, Alamol Huda Street
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2020-10-03, 1399/07/12
Ethics committee reference number
IR.arakmu.REC.1399.208

Health conditions studied

1

Description of health condition studied
Corneal abrasion
ICD-10 code
S05.0
ICD-10 code description
Injury of conjunctiva and corneal abrasion without foreign body

Primary outcomes

1

Description
Corneal abrasion
Timepoint
Immediately after anesthesia, when leaving the recovery room, 24 hours after surgery
Method of measurement
Fluorescein paper and a flashlight with a cobalt blue light filter are used to assess corneal abrasion.

Secondary outcomes

1

Description
Ophthalmic discomfort
Timepoint

24 hours after surgery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group1: As soon as anesthesia and blinking reflex disappears, in the first group, eye care is given with vitamin A so that the researcher first washes his hands and wears clean gloves, then his thumb near the lower eyelid. Apply a gentle pressure to the cheekbones and lower the eyelid to fully expose the conjunctival sac. Then apply vitamin A ointment to the patient's eye without contact with the eyelid or eyelashes and place in the bag. The conjunctiva is placed 1 cm long so that it covers the surface of the eye and then closes the patient's eye with the hand.

Category

Prevention

2

Description

Intervention group 2: As soon as anesthesia and blinking reflex disappears, in the second group, eye care is given with Liposic gel so that the researcher first washes his hands and wears clean gloves, then his thumb near the lower eyelid. Apply a gentle pressure to the cheekbones and lower the eyelid to fully expose the conjunctival sac. Then apply Liposic gel to the patient's eye without contact with the eyelid or eyelashes and place in the bag. The conjunctiva is placed 1 cm long so that it covers the surface of the eye and then closes the patient's eye with the hand

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Valiasr education and treatment center

Full name of responsible person

Nazanin Amini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Nazanin Amini

Position

MSc nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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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