Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of ocular complications following the use of Vitamin A and simple eye topical ointment in non-ophthalmic surgery during general anesthesia

Protocol summary

Summary

Aim of Study: In this study, we will compare the effect of Vitamin A and simple eye ointment based on Paraffin in patients undergoing general anesthesia for non-ophthalmic surgery . Study design: Randomized, double-blind, controlled with a single eye ointment to both eyes, single-center. Inclusion criteria: All patients undergoing general anesthesia for non-ophthalmic surgery are being studied. Exclusion criteria: Patients who have a history of ocular surgery; Patients who wear eye contact lenses; Patients who have visual acuity of less than 20/100; patients who have a history of ocular disease; Patients who are allergic to adhesive tape or have a history of eye ointment; Pregnant Women; Patients with conjunctivitis; ocular prosthesis; ocular hypoperfusion secondary to hypotension or anemia or using a beta blocker and a diuretic such as hydrochlorothiazide due to decrease in tear production base are excluded. Sample size: 130 Intervention Study: The only two common ways of medical treatment will compare. Study outcome: To reduce ocular complications in patients undergoing general anesthesia for non-ophthalmic surgery by taking a more effective ointment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072418581N1**
Registration date: **2015-12-11, 1394/09/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-12-11, 1394/09/20

Registrant information

Name

Seyedeh Sara Bayesh

Name of organization / entity

Islamic Azad University, Tehran Medical Sciences Branch, Tehran, Iran

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigators

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ocular complications following the use of Vitamin A and simple eye topical ointment in non-ophthalmic surgery during general anesthesia

Public title

Ocular complications following the use of Vitamin A and simple eye ointment in non- ophthalmic surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: In this study, all patients undergoing general anesthesia for non-ophthalmic surgery are being studied. Exclusion criteria: Patients who have a history of ocular surgery; Patients who wear eye contact lenses; Patients who have visual acuity of less than 20/100; patients who have a history of ocular disease; Patients who are allergic to adhesive tape or eye ointment; Pregnant Women; Patients with conjunctivitis; ocular prosthesis; ocular hypoperfusion secondary to hypotension or anemia or using a beta blocker and a diuretic such as hydrochlorothiazide due to decrease in tear production base are excluded.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Using the random blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Medical Sciences Branch

Street address

Tehran Medical Sciences Branch, Islamic Azad University, Khaghani St, Shariati Ave

City

Tehran

Postal code

19395/1495

Approval date

2014-11-15, 1393/08/24

Ethics committee reference number

93/8-1033

Health conditions studied

1

Description of health condition studied

Eye pain, Blurry vision, Tearing, Red eye, Photophobia, Foreign body sensation, Allergic reactions, Periorbital edema, Itchy, Sticking of the eyes together, Conjunctiva hyperemia, Scleral erythema, Corneal erosions

ICD-10 code

H59.9

ICD-10 code description

Postprocedural disorder of eye and adnexa, unspecified

Primary outcomes

1

Description

Any type of eye complications as eye pain, Blurry vision, Tearing, Red eye, Photophobia, Foreign body sensation, Allergic reactions, Periorbital edema, Itchy, sticking of the eyes together, Conjunctiva hyperemia, Scleral erythema, Corneal erosions

Timepoint

3to5 hours after general anesthesia, within the 24 hours after anesthesia, after discharge, more investigating in case of any complications

Method of measurement

Visual Analog Scale(VAS), Snellen Eye Chart, Schirmer's test,Scoring system for periorbital oedema, Oxford Schema

Secondary outcomes

1

Description

-

Timepoint

3to5 hours after general anesthesia, within the 24 hours after anesthesia, after discharge, more investigating in case of any complications

Method of measurement

Visual Analog Scale(VAS), Snellen Eye Chart, Schirmer's test, Scoring system for periorbital oedema, Oxford Schema

Intervention groups

1

Description

Intervention group1: (Two standards common types of eye ointments simultaneously into one patient's eye during general anesthesia). Vitamin A ointment (Xerovit, containing 250 units per gram of vitamin A palmitate at the base of Vaseline) without tape into one eye and simple eye ointment(Lubratex, Yellow Soft Paraffin 80 g, Wool Fat 10 g, Liquid Paraffin QS to 100 g) without tape is applied into another eye of patients (A thin layer of ointment approximately one centimeter is placed inside the lower eyelid during anesthesia).

Category

Prevention

2

Description
Intervention group 2: (one type of common standard eye ointment into both patient's eye during general anesthesia). Vitamin A ointment is applied into both eyes of patients and simple eye ointment into both eyes of patients (A thin layer of ointment approximately one centimeter is placed inside the lower eyelid during anesthesia).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Boo-Ali Hospital
Full name of responsible person
Dr Farshid Gholami/Anesthesiologist/Assistant professor/Member of science committee in Islamic Azad
Street address
Boo- Ali Hospital, Damavand St, Emam Hossein Sq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Azad University of Medical Sciences
Full name of responsible person
Dr Hassan Eftekharardebili
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Tehran Medical Sciences Branch, Islamic Azad University, Khaghani St, Shariati Ave
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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
Vice chancellor for research, Azad 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

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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