

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of Corneal methods protection during general anesthesia for functional endoscopic sinus surgery

Protocol summary

Study aim

Comparison of Corneal methods protection during general anesthesia for functional endoscopic sinus surgery

Design

Randomized double-blind clinical trial

Settings and conduct

In patients of intervention group one, after implantation, the patient's eyelid endotracheal tube will be fixed with standard anti-allergy adhesive. In such a way that the patient's cornea is not exposed to air. In patients in intervention group two, after endotracheal intubation, sterile gauze moistened with normal saline is placed on each eyelid and then the eye pad on the sterile gauze will be fixed with glue. For patients in intervention group three, 0.5 cc of vitamin A ointment (Mahia Daroo, Iran) is used in each eye. In patients in intervention group four, 0.5 cc of hydrophilic gel (Bausch & Lomb Incorporated, Singapore) will be used in each eye to protect the cornea.

Participants/Inclusion and exclusion criteria

Patients undergoing sinus surgery by endoscopy ASA I-II. History of any eye disease History of ocular trauma or any congenital or acquired abnormality Any type of eye surgery Pregnancy History of using any type of contact lens in the last week.

Intervention groups

In patients of intervention group one, after implantation, the patient's eyelid endotracheal tube will be fixed with standard anti-allergy adhesive. In such a way that the patient's cornea is not exposed to air. In patients in intervention group two, after endotracheal intubation, sterile gauze moistened with normal saline is placed on each eyelid and then the eye pad on the sterile gauze will be fixed with glue. For patients in intervention group three, 0.5 cc of vitamin A ointment (Mahia Daroo, Iran) is used in each eye. In patients in intervention group four, 0.5 cc of hydrophilic gel (Bausch & Lomb Incorporated, Singapore) will be used in each eye to protect the

cornea.

Main outcome variables

Retinopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N114**

Registration date: **2021-04-10, 1400/01/21**

Registration timing: **prospective**

Last update: **2021-04-10, 1400/01/21**

Update count: **0**

Registration date

2021-04-10, 1400/01/21

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-18, 1400/01/29

Expected recruitment end date

2021-05-03, 1400/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of Corneal methods protection during general anesthesia for functional endoscopic sinus surgery

Public title
Comparison of Corneal methods protection during general anesthesia for functional endoscopic sinus surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing sinus surgery by endoscopy ASA I-II
Exclusion criteria:
History of any eye disease History of ocular trauma or any congenital or acquired abnormality Any type of eye surgery Pregnancy History of using any type of contact lens in the last week

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
72 patients in the 4 study groups and 18 blocks of four permutations, enter a random list of sealedenvelope.com which is extracted from the site. Researchers, including ophthalmologists and statisticians, are not informed about the patient group. After collecting the forms, according to the randomized list, each patient's group is registered on the form.

Blinding (investigator's opinion)
Single blinded

Blinding description
Ophthalmologist at the time of corneal examination after surgery and statisticians do not know how to assign study groups, after collecting the forms, according to the randomized list, each patient's group is registered on the form.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2021-02-28, 1399/12/10

Ethics committee reference number

IR.SUMS.MED.REC.1398.654

Health conditions studied

1

Description of health condition studied

functional endoscopic sinus surgery

ICD-10 code

J01

ICD-10 code description

Acute sinusitis

Primary outcomes

1

Description

Retinopathy

Timepoint

After transfer to the patient to the recovery room

Method of measurement

fluorescein eye stain test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In patients of intervention group one, after implantation, the patient's eyelid endotracheal tube will be fixed with standard anti-allergy adhesive. In such a way that the patient's cornea is not exposed to air.

Category

Prevention

2

Description

Intervention group: In patients in intervention group two, after endotracheal intubation, sterile gauze moistened with normal saline is placed on each eyelid and then the eye pad on the sterile gauze will be fixed with glue.

Category

Prevention

3

Description

Intervention group: For patients in intervention group three, 0.5 cc of vitamin A ointment (Mahia Daroo, Iran) is used in each eye.

Category

Prevention

4

Description

Intervention group: In patients in intervention group four, 0.5 cc of hydrophilic gel (Bausch & Lomb Incorporated, Singapore) will be used in each eye to protect the cornea.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Laleh Dehghan Pisheh

Street address

Khalili Hospital, Khalili Street

City

Shiraz

Province

Fars

Postal code

7193636981

Phone

+98 71 3629 1470

Email

khalili@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaieanzadeh

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences,

Zand street

City

Shiraz

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Postal code

7134844119

Phone

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Email

vcrd@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Shahin Hakimi

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

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7134844119

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+98 71 3647 4270

Email

masihfarzaneh@yaoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Laleh Dehghan Pisheh

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

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City

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lalehdehghan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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masihifarzaneh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is against the policies of the center.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available