

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Superficial Keratotomy on Reducing Postoperative Pain Following Conjunctival Flap ;a Randomized Clinical Trial

Protocol summary

Study aim

To assess whether adding superficial keratotomy to the standard method of conjunctival flap is or is not associated with reduced posoperative pain

Design

Clinical trial with control and intervention group in parallel and double blind, phase 3 is performed on 16 patients. For random assignment of patients to two groups, quadruple randomization blocks will be used:Balanced randomisation blocks

Settings and conduct

A randomized clinical trial will be performed at Hazrat Rasool Akram Hospital. In the first group, the same classical method of conj flap surgery is used and in the second group, conj flap surgery is performed with incision of the superficial radial nerves of the cornea. The pain of these two groups will be measured using visual analogue scale, after 6 hours, 24 hours and 48 hours and finally the average pain reduction in the two groups will be compared. Researcher number two is responsible for asking the patient is unaware that the patient belongs to the intervention or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteri: Patients who are candidates for prosthesis implantation exclusion criteria: painful vision loss eye Patients who are candidates for conjunctival flap with indications other than implant placement (such as pain due to corneal ulcers)

Intervention groups

Patients are divided into two groups. In the first group, we use the classical Gunderson technique as the surgical procedure of choice. In the second group, we use the modified surgical method, conj flap operation with cutting the superficial nerves of the cornea. After 6 hours, 24 hours and 48 hours after surgery, both groups of patients are asked to express their pain on the VAS scale.

Main outcome variables

Pain score based on VAS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054640N2**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

Registration date

2022-05-14, 1401/02/24

Registrant information

Name

Nasser Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-08-20, 1401/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Superficial Keratotomy on Reducing Postoperative Pain Following Conjunctival Flap ;a Randomized Clinical Trial	
Public title	Effect of Superficial Keratotomy on Reducing Postoperative Pain Following Conjunctival Flap.
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: VLE (vision loss eye) Patients who are candidates for prosthesis implantation Exclusion criteria: Patients who are candidates for conjunctival flap with indications other than implant placement (such as pain due to corneal ulcers, etc.) painful vision loss eye
Age	No age limit
Gender	Both
Phase	3
Groups that have been masked	• Participant • Outcome assessor
Sample size	Target sample size: 16 More than 1 sample in each individual Number of samples in each individual: 8 In the control group, we use the classical Gunderson technique as the surgical procedure . In the intervention group, we use the modified surgical method, the conj flap operation with cutting the superficial nerves of the cornea.
Randomization (investigator's opinion)	Randomized
Randomization description	For random assignment of patients to two groups, random codes in balanced quadruple blocks will be used as follows: 1.AA BB 2.AB AB 3.BB AA 4.BA BA
Blinding (investigator's opinion)	Double blinded
Blinding description	Researcher number two is responsible for asking how much pain the patient has at 6 24 48 hours after the operation and at the time of question he is unaware that the patient belongs to the intervention or control group. (Blind access)
Placebo	Not used
Assignment	Parallel
Other design features	Patients are divided into two groups. In the first group, we use the classical Gunderson technique as the surgical procedure . In the second group, we use the modified surgical method, the conj flap operation with cutting the superficial nerves of the cornea. All surgeries are performed under general anesthesia. In surgery, a knife is used and the depth of the incisions is enough to reach

the midd stroma. Trephinen will also be used in cases where the diameter of the cornea is higher than 8 mm. It will be used and we will cut it. After the pan-pressure operation, pressure will be applied for three days and 5 acetaminophen tablets will be prescribed for all patients with a prescription every 4 hours. If the patient needs more painkillers, in Patient data are recorded. Due to the fact that the patient's eye is bandaged in the first three days, we will not use topical corticosteroids for up to three days after opening the bandage, which coincides with the first visit on the third day after surgery. Topical steroid drops should be started four times a day for the patient and no oral corticosteroids should be used. The title of the cutting guide will be used after the trephinen horizontal and vertical cuts on the surface of the century One will be done by the surgeon with a knife at the same depth of 300. In cases where the diameter of the cornea is less than 8 mm, the surgeon tries to extend the incision depth to the middle of the stroma. After 6 hours, 24 hours and 48 hours after surgery, both groups of patients are asked to express their pain on the VAS scale. Visual analogue scale (VAS) is one of the best methods available for estimating pain intensity. VAS is a 10 cm line printed on a piece of paper with a marker at the end. It is "painless" at one end and "worst pain" or "indescribable pain" at the other. The patient places a mark on the line to indicate pain, and then the mark is measured with a ruler to obtain a score. The mean scores of the two groups are calculated using the Tscore method and finally the mean postoperative pain intensity in the two selected groups will be compared.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran university of medical sciences

Street address

Niyayesh St., Satarkhan St.

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2022-03-18, 1400/12/27

Ethics committee reference number

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Severe visual impairment, monocular
ICD-10 code
H54.5
ICD-10 code description
Severe visual impairment, monocular

Primary outcomes

1

Description

In the study of the effect of superficial corneal incisions in reducing pain in patients after conjunctival flap surgery, primary outcome can be the pain score after Corneal neurotomy .

Timepoint

In the study of the effect of superficial corneal incisions in reducing pain in patients after conjunctival flap surgery, pain score measurement can be 6 24 48 hours after corneal neurotomy

Method of measurement

In studying the effect of superficial corneal incisions in reducing pain in patients after conjunctival flap surgery, how to measure pain score can be using VSA(visual analogue scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:we use the modified surgical method, the conj flap operation with cutting the superficial nerves of the cornea.

Category

Prevention

2

Description

Control group:we use the classical Gunderson technique as the surgical procedure

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Nasser Karimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

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?

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr.Nasser Karimi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

We intend to share the results as an article

When the data will become available and for how long

At the end of project 1 year

To whom data/document is available

All

Under which criteria data/document could be used

All academic research

From where data/document is obtainable

Dr karimi instagram @drnasserkarimi

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

Within 1 week of request

Comments