Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of vitamin A ophthalmic ointment on reducing pain and accelerating the recovery of corneal abrasions after photorefractive keratectomy

Protocol summary

Study aim
Investigating the effect of vitamin A ophthalmic ointment on reducing pain and accelerating the recovery of corneal abrasions after photorefractiokeratectomy surgery.

Design
Clinical trial with random permutation block method, phase 3 on 28 patients, which are analyzed and used for randomization using SPSS version 22.

Settings and conduct
Patients will undergo photorefractiokeratectomy with knowledge and consent in the company's study using an excimer device, and they are also free to withdraw from the study at any stage. Their sex, medical history is collected.

Participants/Inclusion and exclusion criteria
Entry criteria: American Society of Anesthesiology class I and II People with refractive error myopia and regular astigmatism (both together or each one alone) The amount of optical zone 5.6 - 5.7, people with spherical equivalent maximum of 3.5 diopters. Exclusion criteria: lack of consent to participate in the study, use of contact lenses in the last two months, presence of corneal scratches before surgery, drug use Corneal dystrophies, the presence of any structural disorders of the eye, the presence of pathologies and eye diseases, the presence of systemic diseases (diabetes, vascular collagen disorder, etc.), people with hyperopia, amblyopia

Intervention groups
These patients randomly received routine drugs such as chloramphenicol, betamethasone and artificial tears in one eye (control group) and in the other eye as an intervention group, in addition to routine drugs, received sterile vitamin A eye ointment from Iran Nazo brand every 8 hours. It will be a month.

Main outcome variables
Visual Analog Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240213060989N1**
Registration date: **2024-03-04, 1402/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2024-03-04, 1402/12/14**
Update count: **0**

Registration date
2024-03-04, 1402/12/14

Registrant information

Name
Maryam Hajizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 916 131 3548

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hajizadeh-m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-29, 1402/12/10

Expected recruitment end date
2024-10-31, 1403/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of vitamin A ophthalmic ointment on reducing pain and accelerating the recovery of corneal abrasions after photorefractive keratectomy

Public title
Investigating the effect of vitamin A ophthalmic ointment on reducing pain after refractive keratectomy surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Class I and II of the American Society of Anesthesiology People with refractive error myopia and regular astigmatism (both together or each one alone) The optical amount of the zone is 5.6 - 5.7 People with spherical equivalent maximum 3.5 diopters
Exclusion criteria:
Lack of consent to participate in the study Use of contact lenses in the last two months Presence of corneal scratch before surgery taking medication Corneal dystrophies The presence of any structural disorder of the eye Pathology and eye diseases Existence of systemic diseases (diabetes, vascular collagen disorder, etc.) People with hyperopia, amblyopia

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of patients randomly (using permutation blocks) into two intervention and witness groups (14 people) in such a way that patients will participate in the study with knowledge and consent, based on this, the number of patients who will undergo surgery There are 28 people. PRK was performed by a surgeon and will be included in the study. Then, in these patients, in one eye, routine betas from the family of chloramphenicol, betamethasone and artificial tears (control group) and in the other eye as an intervention group, in addition to routine drugs, received Vitamin A Sterile Eye Ointment from Iran Nazo brand requires every 8 hours to a month and can explain to the drugs that it is possible to take the drug as a drug, then from surgery for patients who want to be able to relieve their pain afterwards. Do. (6 and 24 hours after the operation, 12 and 24 hours after the operation and then daily up to a week) and the time period when the pain starts after the operation and requires the use of painkillers after that and the number of painkillers It consumes extra. Register themselves in the checklist that will be delivered to them on the day of the operation

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Jundishapur University of Medical Sciences, Ahvaz
Street address
Jundishapur University of Medical Sciences، Koi Golestan، Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673166

Approval date
2024-01-27, 1402/11/07

Ethics committee reference number
IR.AJUMS.REC.1402.609

Health conditions studied

1

Description of health condition studied
Pain reduction after Photorefractive keratectomy surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Visual Analog Scale (VAS)

Timepoint
Immediately after the operation, 6, 12 and 24 hours

Method of measurement
It will be quantitatively recorded from 0 (no pain) to 5 (very intense pain that is excruciating).

Secondary outcomes

1

Description
Corneal scratch

Timepoint

Examination by hand-held slit lamp In the daily visits after the surgery (until the complete recovery of the corneal scratch) and then a re-visit will be done one week after the surgery.

Method of measurement

Based on mm

2

Description

Time of onset of first pain

Timepoint

Based on the patient condition checklist

Method of measurement

Time of onset of first pain after surgery

3

Description

Patient's eye complaint

Timepoint

Based on the patient condition checklist

Method of measurement

subjectively and comparing binoculars

Intervention groups

1

Description

control group: In these patients, routine drugs such as chloramphenicol, betamethasone and artificial tears are used randomly in one eye every 8 hours for a month.

Category

Treatment - Drugs

2

Description

Intervention group: In the other eye, as an intervention group, in addition to routine medications, they will receive vitamin A sterile eye ointment from Iran Nazo brand every 8 hours for a month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Maryam Hajizadeh

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24 metery street, east sahely highway, ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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University of medical science, Golestan street, Golestan town، Ahvaz

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Maryam Hajizadeh

Position

Assistant Professor of Glaucoma

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor of Glaucoma
Latest degree
Subspecialist
Other areas of specialty/work
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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