

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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 photorefractikeratectomy 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 photorefractikeratectomy 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)

##### Phone

+98 916 131 3548

##### Email address

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**

Khuzestan

**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

**Street address**

24 metery street, east sahely highway, ahvaz

**City**

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Khuzestan

**Postal code**

6193673166

**Phone**

+98 916 131 3548

**Email**

hajizadeh-m@ajums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mehrnoosh Zakerkish

**Street address**

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

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**Province**

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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

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

Ahvaz University of Medical Sciences

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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