Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

effect of balanced salt solution temperatures in pain control and corneal epithelium healing after photorefractive keratectomy

Protocol summary

Study aim
effect of balanced salt solution temperatures (24 degree & 0 degree) on pain control after photorefractive keratectomy

Design
This is a contralateral clinical trial and is conducted on 116 eligible patients. For randomization, the lottery method is used in such a way that two completely folded papers are placed in a container. The left eye is written on one paper and the right eye is written on the other paper. In another container, two folded papers are placed, on one paper the control group is written and on the other paper, the intervention group is written. After mixing, he takes a piece of paper from each container and surgery will be performed based on the content of the paper.

Settings and conduct
this study is carried out in a period of 6 months in khatam al_anbia hospital in mashhad.

Participants/Inclusion and exclusion criteria
inclusion criteria include patients aged 20 to 40 years and patients with myopia and myopic astigmatism exclusion criteria include patients with a history of diabetes and rheumatology diseases and smoking & opioid use .

Intervention groups
this contralateral study is conducted on 116 selected patient . the study is that in one eye during and after photorefractive keratectomy balanced salt solution is poured at room temperature and in the other eye BSS at zero degree temperature is poured.

Main outcome variables
The degree of pain after photorefractive keratectomy, the degree of restoration of the corneal epithelium after photorefractive keratectomy, the degree of inflammation and redness of the conjunctiva after photorefractive keratectomy and the patient's refraction after photorefractive keratectomy

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231114060059N1**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **retrospective**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date
2025-11-18, 1404/08/27

Registrant information
Name
hossein hajizade juybary
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 4254 6171
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-08-22, 1403/06/01
Expected recruitment end date
2025-01-20, 1403/11/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

effect of balanced salt solution temperatures in pain control and corneal epithelium healing after photorefractive keratectomy

Public title
Investigating the effect of balance salt solution temperature zero degrees on pain control after photorefractive keratectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
pation with myopia and myopic astigmatism the degree of myopia is 1 to 5 diopters the amount of astigmatism is 0 to 4 diopters
Exclusion criteria:
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator

Sample size
Target sample size: **116**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
the researcher is unaware of solutions temperature but the patient and outcome assessor are informed about the temperature.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of mashhad University of Medical Sciences
Street address
Gharani Blvd, khatam ol anbia hospital
City
Mashad
Province
Razavi Khorasan
Postal code
۹۱۹۵۹۶۴۶۴۵
Approval date
2024-05-27, 1403/03/07
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1403.066

Health conditions studied

1

Description of health condition studied
Refractive error
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain level after photorefractive keratectomy
Timepoint
Within 5 days after photorefractive keratectomy
Method of measurement
Pain level after photorefractive keratectomy based on visual analogue scale in 6 hours after photorefractive keratectomy and on days 1, 3 and 5 after photorefractive keratectomy

2

Description
Corneal epithelium repair rate after photorefractive keratectomy
Timepoint
Within 5 days after photorefractive keratectomy
Method of measurement
The amount of epithelium repair based on the remaining defect area with Slate Photo on days 1, 3 and 5 after photorefractive keratectomy

Secondary outcomes

empty

Intervention groups

1

Description
In this study, in one patient's eye, room temperature balanced salt solution is poured during and after photorefractive keratectomy (control group) and in the other eye, zero degree balanced salt solution is poured during and after photorefractive keratectomy (intervention group).
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
khatam ol anbia hospital

Full name of responsible person
mohammadreza sedaghat

Street address
shahid gharani blvd

City
mashhad

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9195964645

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+98 51 3728 1401

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sedaghatMR@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
mohamadreza sedaghat

Position
ophthalmologist cornea fellowship professor of ophthalmologhy mashhad university of medical sciences

Latest degree
Specialist

Other areas of specialty/work
Ophthalmology

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Person responsible for updating data

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Email

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable