

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Email address

hosseinhajizade6171@gmail.com

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	
<u>1</u>	
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	91190964640

Approval date	2024-05-27, 1403/03/07
Ethics committee reference number	IR.MUMS.MEDICAL.REC.1403.066
Health conditions studied	
<u>1</u>	
Description of health condition studied	Refractive error
ICD-10 code	
ICD-10 code description	
Primary outcomes	
<u>1</u>	
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
<u>2</u>	
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	
<u>1</u>	
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

Province

Razavi Khorasan

Postal code

9195964645

Phone

+98 51 3728 1401

Email

sedaghatMR@mums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

mohammadreza sedaghat

Street address

shahid gharani blvd

City

mashhad

Province

Razavi Khorasan

Postal code

9195964545

Phone

+98 51 3728 1401

Email

sedaghatMR@mums.ac.ir

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

mohammadreza sedaghat

Position

ophthalmologist cornea fellowship professor of ophthalmology mashhad university of medical sciences

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

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shahid gharani blvd

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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

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