Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Clinical results comparison of mechanical and transepithelial debridement in photorefractive keratectomy

Protocol summary

Summary

Photorefractive keratectomy (PRK) is a kind of refractive error surgery with a long history in refractive error corrections. There are several ways for epithelial debridement before stromal ablation. In this study, we compared clinical factors such as operation time, rate of re epithelialization, postoperative pain, refractive error, epithelial defect, intraocular pressure, contrast acuity, uncorrected and best corrected acuity in mechanical (m-PRK) and trans epithelial PRK (t-PRK). This comparative study included 80 eyes of 40 patients with myopia and mean age of 31.22+-8.7 (ranged from 20 to 55) years. After complete preoperative examinations, mechanical technique was done in one eye randomly and transepithelial technique in the contralateral eye. All postoperative clinical factors were measured and recorded in 6 months. The inclusion criteria was patients with myopia up to 8.00D and have trend for doing PRk, with normal corneal thickness, normal IOP, normal epithelium and endothelium, and... the exclusion criteria was patients with anterior or posterior segment pathology, progressive refractive error, keratoconus, history of any ocular surgery and...

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072930249N1**
Registration date: **2017-09-22, 1396/06/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-22, 1396/06/31

Registrant information

Name

Javad Heravian Shandiz

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6722

Email address

heraviansj@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Grant

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical results comparison of mechanical and transepithelial debridement in photorefractive keratectomy

Public title

Clinical results comparison of mechanical and transepithelial debridement in photorefractive keratectomy

Purpose

Diagnostic

Inclusion/Exclusion criteria

The inclusion criteria was patients with myopia up to 8.00D and have trend for doing PRk; with normal corneal thickness; normal IOP; normal epithelium and

endothelium; clear medias; leaving wearing soft contact lenses for two weeks and hard contact lenses for three month; have normal tear quantity and quality; the exclusion criteria was patients with anterior or posterior segment pathology; progressive refractive error; keratoconus; history of any ocular surgery; amblyopia; dry eye

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical sciences

Street address
Department of Optometry, School of Paramedical Sciences

City
Mashhad

Postal code

Approval date
2017-07-15, 1396/04/24

Ethics committee reference number
IR.MUMS.REC.1396.130

Health conditions studied

1

Description of health condition studied
Refractive surgery

ICD-10 code
H57.8

ICD-10 code description
Other specified disorders of eye and adnexa

Primary outcomes

1

Description
Postoperative pain assessment

Timepoint
The first, third, fifth and first, third and sixth months after surgery

Method of measurement
Using 11-point numeric scale of pain and eye sensation scale questionnaires

Secondary outcomes

1

Description
UCVA, refraction, BCVA, keratometry, bio microscopy, tear quantity, contrast acuity, IOP

Timepoint
The first, third and sixth months

Method of measurement
Visual acuity chart, auto refractometer, keratometer, slit lamp, schirmer test 1, Vector Vision CSV 1000, tonometer

Intervention groups

1

Description
PRK surgery

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Al Anbia Hospital in Mashhad

Full name of responsible person
Dr. Siamak Zarei

Street address

City
mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Javad Heravian

Street address
Department of Optometry, School of Paramedical Sciences, Mashhad University of Medical sciences

City
mashhad
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Javad Heravian
Position
Professor and director of optometry department of Paramedical School
Other areas of specialty/work
Street address
University compound
City
mashhad
Postal code
Phone
+98 51338846722
Fax
Email
heraviansj@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Paramedical Sciences, Mashhad University of Medical sciences, Mashhad, Iran
Full name of responsible person
Professor Javad Heravian
Position
Professor of Optometry
Other areas of specialty/work
Street address
Ferdowsi University campus
City
mashhad
Postal code
Phone
+98 51338846722
Fax
Email
heraviansj@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Javad Heravian
Position
Professor and director of optometry department of Paramedical School
Other areas of specialty/work
Street address
Azadi Square - Campus University - Faculty of Paramedicine
City
mashhad
Postal code
Phone
+98 51338846722
Fax
Email
heraviansj@mums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty