# 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**

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**Name of organization / entity**

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**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

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Department of Optometry, School of Paramedical Sciences, 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**
*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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*