

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Efficacy and Safety of Trans Epithelial Compared to Conventional Photorefractive Keratectomy for Treatment of Astigmatism of more than 3 Diopters.

Protocol summary

Study aim

To determine efficacy and safety of trans-epithelial photorefractive keratectomy (TPRK) compared to conventional PRK for treatment of astigmatism.

Design

Parallel, randomized double blind clinical trial, with contralateral control group.

Settings and conduct

Feiz Hospital and Parsian Eye Clinic, Isfahan, Iran. The subjects, outcome assessor, and data analyzer will be blinded with regard to grouping.

Participants/Inclusion and exclusion criteria

Inclusion: -over 18 years old -spherical error equal to or greater than -1 diopter and cylinder equal to or greater than 3 diopters in both eyes with minus cylinder notation -Stable refraction during the last year -No history of wearing contact lens for at least 3 weeks -No history of Keratoconus and any type of corneal ectasia in the patient or his first-degree relatives. Exclusion: -Previous ocular surgery -Active eye disease -History of severe eye trauma -Systemic diseases that potentially impair wound healing -Taking inhaled or systemic steroids currently or in the last 3 months

Intervention groups

One eye, in each subject will randomly be assigned to the TPRK group, and the other eye will be treated with conventional PRK.

Main outcome variables

Astigmatic treatment indices, Cornea slit-lamp examination, Post-operative visual acuity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130306012724N5**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Alireza Peyman

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-05-21, 1400/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and Safety of Trans Epithelial Compared to Conventional Photorefractive Keratectomy for Treatment of Astigmatism of more than 3 Diopters.

Public title

Trans Epithelial PRK for Treatment of High Astigmatic Error

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Stable refraction during the last year
No history of wearing contact lens for at least 3 weeks before the examination No history of Keratoconus and any type of corneal ectasia in the patient or his first-degree family sphere equal to or greater than -1 diopter and cylinder equal to or greater than 3 diopters in both eyes Satisfaction and full knowledge of patients to enter the plan

Exclusion criteria:

Previous ocular surgery Active eye disease, corneal dystrophy, retinal diseases, glaucoma, dry eye of any degree History of severe eye trauma Systemic diseases that potentially impair wound healing, including diabetes, collagen vascular disease, and pregnancy. Taking inhaled or systemic steroids actively or for 3 months before the procedure

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each patient, both eyes are operated on

Randomization (investigator's opinion)

Randomized

Randomization description

In a contralateral design, one eye of each subject will be assigned randomly to the study group, and the other eye of the same patient be assigned to the control group, by Random Allocation Software. Random allocation table created by "Random Allocation Software" version 1.0.0 (developed by M. Saghaei, MD, Isfahan University of Medical Sciences). The number of groups set at 2 (namely OD, and OS), sample size: 40, on only one block, to find which eye of the sequential case numbers will be assigned to the intervention group. The excimer device operator will have the random table; at the time of surgery, one eye will be assigned to the intervention group, and the contralateral eye to the control group, according to the allocation table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Subjects know eyes will be operated with two techniques, they will not know which eye is operated by

which way. The outcome assessor and data analyzer will be blinded with regard to grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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Hezarjerib Street

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Approval date

2020-10-24, 1399/08/03

Ethics committee reference number

IR.MUI.MED.REC.1399.649

Health conditions studied**1****Description of health condition studied**

Myopia

ICD-10 code

H52.13

ICD-10 code description

Myopia, bilateral

2**Description of health condition studied**

Astigmatism

ICD-10 code

H52.203

ICD-10 code description

Unspecified astigmatism, bilateral

Primary outcomes**1****Description**

Refractive astigmatism

Timepoint

Before, and 6 months after intervention

Method of measurement

Autorefractometry, combined with subjective refinement

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feiz@mui.ac.ir

Secondary outcomes

1

Description

Visual acuity

Timepoint

Before, and 6 months after intervention

Method of measurement

Snellen chart

2

Description

Cornea slit-lamp examination

Timepoint

before, and 6 months after intervention

Method of measurement

Slit-lamp bio-microscopy

Intervention groups

1

Description

Intervention group: Trans-epithelial PRK for treatment of myopic astigmatism with SCHWIND AMARIS 1050RS (eye-tech-solutions, Kleinostheim, Germany) excimer laser system.

Category

Treatment - Surgery

2

Description

Control group: Conventional PRK for treatment of myopic astigmatism with SCHWIND AMARIS 1050RS (eye-tech-solutions, Kleinostheim, Germany) excimer laser system aberration free profile.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz hospital

Full name of responsible person

Alireza Peyman

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Modarres Street., Ghods Square

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Phone

2

Recruitment center

Name of recruitment center

Parsian Eye Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Research dept., Isfahan University of Medical Sciences, Hezar-Jerib Ave., Isfahan, IR Iran

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Leila Babaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

All researchers who are interested

Under which criteria data/document could be used

Selected researchers

From where data/document is obtainable

Contact principal investigator

What processes are involved for a request to access data/document

Maximum one month after contacting the principal investigator

Comments