

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Trans Epithelial Phototherapeutic keratectomy (TE_PTK) in correction of irregularities after refractive surgery

Protocol summary

Study aim

Determining the refractive error of patients (including the amount of sphere and cylinder and cylinder axis) and determining the corrected vision before and after Trans epithelial Phototherapeutic Keratectomy

Design

The sample size was calculated using G Power software for 30 samples. In this study, there is no control group and therefore there was no need for blinding and the results are compared with studies in the American book.

Settings and conduct

Among the patients referred to the Nikookari Eye Hospital of Tabriz University of Medical Sciences; patients who have undergone refractive surgery and have reduced vision by 2/10 to 9/10 and visual symptoms such as halo or diplopia and in the corneal epithelial map Irregularities in the corneal epithelium are included in the study if desired and with informed consent (TE-PTK) using a Excimer laser with a wavelength of 193 nm using local anesthesia in the operating room. dressing lens is placed and antibiotic and betamethasone drops are started for the patient. Their vision and refraction are measured on the first day and the first and third months. Also, the epithelial map is taken from the patient's cornea after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with reduced vision after refractive surgery and completing the informed consent form to participate in the study Exclusion criteria:1.collagen diseases and diabetes 2. Eye surface diseases or dry eyes 3. Patients with ocular pathologies

Intervention groups

For patients with reduced vision after refractive surgery by 2/10 to 9/10 and visual symptoms such as halo or diplopia, Transepithelial Phototherapeutic keratectomy(TE-PTK) is performed using an excimer laser and under local anesthesia.

Main outcome variables

Patients' vision before treatment and the first day and

the first and third months after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051344N2**

Registration date: **2021-12-24, 1400/10/03**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-24, 1400/10/03**

Update count: **0**

Registration date

2021-12-24, 1400/10/03

Registrant information

Name

Afshin Lotfi sadigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3657 7330

Email address

lotfisadigh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-30, 1400/09/09

Expected recruitment end date

2022-02-28, 1400/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Trans Epithelial Phototherapeutic keratectomy (TE_PTK) in correction of irregularities after refractive surgery

Public title

Evaluation of Trans Epithelial Phototherapeutic keratectomy (TE_PTK) in correction of irregularities after refractive surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with low vision after refractive surgery completing informed consent form to participate in the study

Exclusion criteria:

Collagen vascular diseases and Diabetes Ocular Surface Disease or Dry eye Patient with ocular pathology

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Abbasi street

City

Tabriz

Province

East Azarbaijan

Postal code

0154645395

Approval date

2021-11-30, 1400/09/09

Ethics committee reference number

IR.TBZMED.REC.1400.808

Health conditions studied

1

Description of health condition studied

Corneal irregularities after Refractive Surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Visual acuity

Timepoint

Patients' vision is measured before treatment and on the first day after treatment, as well as the first and third months.

Method of measurement

Snellen Chart

Secondary outcomes

1

Description

Refractive error

Timepoint

Patients'refractive error is measured before treatment and on the first day after treatment, as well as the first and third months.

Method of measurement

Autorefractometer

Intervention groups

1

Description

Among the patients referred to the Nikookari Eye Medical Center of Tabriz University of Medical Sciences, patients who have undergone refractive surgery in the past and have reduced vision by 2/10 to 9/10 and also have visual symptoms such as halo or diplopia, and in the Corneal epithelial mapping is irregular in the corneal epithelium. If desired and with informed consent, they are included in the study. Trans epithelial Phototherapeutic Keratectomy is performed using a excimer laser with a wavelength of 193 nm using local anesthesia in the operating room. During this surgery, the corneal epithelium is removed only in irregular areas and then the excimer laser is applied and the dressing lens and antibiotics and betamethasone drops are started for the patient. Their vision and refraction are measured on the

first day and the first and third months. Also, the epithelial map is taken from the patient's cornea after 3 months.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Nikookari Eye Hospital

Full name of responsible person

Afshin Lotfi Sadigh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Mohammad Samiei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

10

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Banafsheh Sarmadi

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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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Hanieh Azizi

Position

Masters

Latest degree

Master

Other areas of specialty/work

Medical Education

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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

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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