

# 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

**Street address**

Abbasi

**City**

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**Province**

East Azarbaijan

**Postal code**

5154645395

**Phone**

+98 41 7330 3657

**Email**

Lotfisdigh@tbzmed.ac.ir

**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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samiei.moh@gmail.com

**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**

Ophthalmology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Afshin Lotfi Sadigh

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

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**Person responsible for updating data**

**Contact**

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Tabriz University of Medical Sciences

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Hanieh Azizi

**Position**

Masters

**Latest degree**

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Medical Education

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Azizih@tbzmed.ac.ir

**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