# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Oral Ascorbate Effect on Corneal Epithelial Healing Time and Haze Formation After Trans_epithelial Photorefractive Keratectomy

### Protocol summary

**Study aim**

Effect of Oral Ascorbate on Corneal Epithelial Quality, Corneal Epithelial Healing Time, Corneal Haze Healing and quantity of patients'pain after Trans_epithelial Photorefractive Keratectomy

**Design**

A randomized clinical trial including two groups (Control group, intervention group), factorial and randomized with blinded outcome assessment, phase3 enrolled for 160 patients by block randomization method by computer.

**Settings and conduct**

Before surgery, all necessary examinations and paraclinical assessments will be done for all candidated patients; also assessments will be done repeatedly in weeks: 1, 2 and months: 2, 3 after surgery.

**Participants/Inclusion and exclusion criteria**

Conditions for Entering the Study: patients candidates for TPRK during the 2022,Junel; pateints'eye score must be stable for at least one year; pateints must be more than 18 and less than 50 years old; because this surgery is completely elective, both this surgery and using vitamin_c must be based on the patient's decisions. Conditions for not entering the study: despite the sufficient and comprehensive explanations, the patients were not interested in participating the study; the patient is dead or suffers from another proved disease.

**Intervention groups**

Group A as *case control* will only receive the common treatment after the surgery which includes using bethamethasone and cloramphenicole drops, 1 drop every 6 hours till the first week after surgery and flucort drop till 10 weeks after surgery (reducing dose after every 2 weeks). Group B as *intervention group* will receive oral chewing tablets of vitamin C 500mg every 6 hours during the first three days after surgery along with the common treatment.

**Main outcome variables**

The main outcome of the study is to survey the relationship between vit_C and healing cornea epithelium after TPRK.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20220601055053N1**
Registration date: **2022-06-20, 1401/03/30**
Registration timing: **retrospective**

Last update: **2022-06-20, 1401/03/30**
Update count: **0**

**Registration date**

2022-06-20, 1401/03/30

**Registrant information**

**Name**

Niloofar Hejazi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 26 3254 8630

**Email address**

niloohjz7@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-05-22, 1401/03/01

**Expected recruitment end date**

2022-06-20, 1401/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Oral Ascorbate Effect on Corneal Epithelial Healing Time and Haze Formation After Trans_epithelial Photorefractive Keratectomy

**Public title**
Oral Vitamin_C Effect in Treatment of Cornea

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients Candidated for TPRK during the 2022, June
Patients' eye score must be stable for at least one year
Patients must be more than 18 and less than 50 years old Because this surgery is completely elective,both this surgery and using vitamin_c must be based on the patient's decisions

**Exclusion criteria:**
The patients were not interested in participating the study despite the comprehensive and complete explanations. The patient is dead or get another proved disease such as collagen vascular diseases,romatoid arthritis,glandular diseases (hypo/hyper thyroidism and hypo/hyper parathyroidism),diabetes mellitus,hypertension,marfan syndrome,herpes keratitis,infectious diseases(HIV,hepatitis),cataract or any other past noticable ophthalmic disease or surgery that destroy the results of study in a way that examination can not be compared and assessed.

**Age**
From **18 years** old to **50 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **160**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The patients are randomly divided into two groups using BLOCK RANDOMIZATION method by the surgical technician(that is present in all surgeries) and the surgeon is not aware of the patients'placement in each group.The patients will be randomly divided into equal numbers by computer.From this number , groupA as case control will only receive the common treatment after the surgery which includes using betamethasone and chloramphenicol drops, 1drop every 6hours till the first week after surgery and fluocort drop till 10 weeks after surgery(reducing dose after every 2weeks).groupB as intervention group will receive oral tablets of vitamin C 500mg every 6hours during the first three days after surgery along with the common treatment.It is necessary to mention that the patients will be explained that they don't need to use any other combinations including vitamin C.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The patients are randomly divided into two groups with equal number of patients by computer using BLOCK RANDOMIZATION method by the surgical technician(that is present in all surgeries) and the surgeon and the researcher are not aware of the patients'placement in each group.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Alborz University of Medical Sciences

**Street address**
Alborz University of Medical sciences, Edari district. North taleghani Blvd., Taleghani square

**City**
Karaj

**Province**
Alborz

**Postal code**
3155734541

**Approval date**
2022-05-21, 1401/02/31

**Ethics committee reference number**
IR.ABZUMS.REC.1401.053

## Health conditions studied

### 1

**Description of health condition studied**
Effect of Ascorbate on Healing Cornea Epithelium after Trans_epithelial Photorefractive Keratectomy

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Corneal Epithelial Healing Time

**Timepoint**
Before the surgery,1week, 2weeks, first, second, third

months after surgery

**Method of measurement**

slit lamp

**2**

**Description**

Corneal Haze Formation

**Timepoint**

Before the surgery,1week, 2weeks, first, second, third months after surgery

**Method of measurement**

slit lamp

**3**

**Description**

Crneal Epithelial Healing Quality

**Timepoint**

Before the surgery,1week, 2weeks, first, second, third months after surgery

**Method of measurement**

slit lamp

**4**

**Description**

The Quantity of Patient's Pain after Surgery

**Timepoint**

Before the surgery,1week, 2weeks, first, second, third months after surgery

**Method of measurement**

The McGill Pain Questionnaire(MPQ)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Control group: they will only receive the common treatment after the surgery which includes using bethamethasone and cloramphenicole drops, 1drop every 6hours till the first week after surgey and flucort drop till 10 weeks after surgery(reducing dose after every 2weeks).

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: they will receive oral chewing tablets of vitamin C 500 mg produced by Simorgh Daru Attar Pharmaceutical indaustry every 6hours during the first three days after surgery along with the common treatment.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Alborz Central Special Clinic

**Full name of responsible person**

Niloofar Hejazi

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Floor2, Mahdieh Street, Tohid Square

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**2**

**Recruitment center**

**Name of recruitment center**

Karaj Shahid Madani Hospital

**Full name of responsible person**

Niloofar Hejazi

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Shahid Madani Square, Mahan Blvd., Jahanshahr

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Dr Hatam Godini

**Street address**

Research assistant,Saffarian Alley,Golshahr district

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**Province**

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**Email**

Research@abzums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Karaj University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Karaj University of Medical Sciences

**Full name of responsible person**

Niloofar Hejazi

**Position**

medicine student(intern)

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Other areas of specialty/work**

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

This survey is such a statistical analysis and our purpose is releasing the inclusion in group results.Personal identities and personal results of patients are unnecessary.

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Final data will be published only as group result.

**When the data will become available and for how long**

The Results of this survey will be accesible 3months after publishment.

**To whom data/document is available**

All the university researchers and also all other applicants in indusries can send request for access to Final data.

**Under which criteria data/document could be used**

Other completing statistical analysis can be done if the researcher of this survey agreed after cosultment.

**From where data/document is obtainable**

Applicants can seend request to the below email address which is for(Dr.Niloofar Hejazi): niloohjz@gmail.com

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

Applicant's emails will be answered at last during one week.

**Comments**