# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## a comparative study of fibrin glue versus suturing on higher order aberration in patients undergoing pterygium excision and free conjunctival autograft

## Protocol summary

**Study aim**
Determination of the effect of pterygium surgery on high order aberrations using fibrin glue and suture

**Design**
two arm parallel groups non randomised trial with non blinded outcome assesment

**Settings and conduct**
patients suffering from pterygium devided into two groups and will undergo surgery one with fibrin glue and the other with suture method and 6 months after that , high order aberratins will be measured by pantacam and results will be compared by the results of presurgery high order aberrations in both groups

**Participants/Inclusion and exclusion criteria**
All patients with pterygium with surgical indication; history of anterior segment surgery, recent ophthalmic trauma, active intraocular inflammation, history of previous pterygium, contact lens use, chronic use of eye drops, corneal disease, dry eye

**Intervention groups**
patients in two groups,one by fibrin glue and the other by suture method will undergo surgery and both will be compared on high order aberations after surgery

**Main outcome variables**
Visual acuity ; Spherical equivalence;Total aberration;Total coma;Total trefoil;total spherical aberrations;total high astigmatism;total quatrefoil

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190129042551N1**
Registration date: **2020-05-13, 1399/02/24**
Registration timing: **retrospective**
Last update: **2020-05-13, 1399/02/24**
Update count: **0**

**Registration date**
2020-05-13, 1399/02/24

**Registrant information**

**Name**
Aminreza Deljooy
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 41 3331 3959
**Email address**
timman.med1994@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-12-22, 1397/10/01

**Expected recruitment end date**
2019-05-21, 1398/02/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
a comparative study of fibrin glue versus suturing on higher order aberration in patients undergoing pterygium excision and free conjunctival autograft

**Public title**
study of high order aberrations in pterygium surgery

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All patients with pterygium that have surgical indication

**Exclusion criteria:**

History of pterygium surgery History of Anterior Segment Surgery Chronic use of eye drops Corneal Diseases using contact lens Active intraocular inflammation Recent Ophthalmic Trauma dry eye

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **45**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee in Research, Tabriz University of Medical Sciences

**Street address**

No.8 , 2th alley , new lida , valiasr town

**City**

tabriz

**Province**

East Azarbaijan

**Postal code**

5157844333

**Approval date**

2020-04-20, 1399/02/01

**Ethics committee reference number**

IR.TBZMED.REC.1399.043

## Health conditions studied

**1**

**Description of health condition studied**

pterygium

**ICD-10 code**

H11.0

**ICD-10 code description**

Pterygium of eye

## Primary outcomes

**1**

**Description**

high order aberrations

**Timepoint**

The beginning of the intervention and 6 months after the surgery

**Method of measurement**

pentacam device

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group 1:after general anesthesia, fibrovascular tissue will be removed and the surface of the cornea will be shaved by razor blade.then the conjunctivolimbal autograft will be taken from conjunctival area of the upper bulb.this outograft will be placed in the desired location by 10-0 nylon suture.after surgery patients will be treated by Betamethasone drop (every 4 hour) and chloramphenicol drop (QID) and Artificial tear drop(every 3 hour) and betamethasone drop drop will be tapered every 2 weeks.aberrometry of patients will be measured before and 6 months after surgery by pantacam.

**Category**

Treatment - Surgery

**2**

**Description**

Intervention group 2:after general anesthesia, fibrovascular tissue will be removed and the surface of the cornea will be shaved by razor blade.then the conjunctivolimbal autograft will be taken from conjunctival area of the upper bulb.this outograft will be placed in the desired location by fibrin glue.after surgery patients will be treated by Betamethasone drop (every 4 hour) and chloramphenicol drop (QID) and Artificial tear drop(every 3 hour) and betamethasone drop drop will be tapered every 2 weeks..aberrometry of patients will be measured before and 6 months after surgery by pantacam.

**Category**

Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Nikookari hospital

**Full name of responsible person**
nazli taheri

**Street address**
No.8 , 2nd alley., new lida street.,valiasr town

**City**
tabriz

**Province**
East Azarbaijan

**Postal code**
5157834333

**Phone**
+98 41 3331 3959

**Email**
timman.med1994@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
ata mahmoodpoor

**Street address**
No. 8 , 2nd alley., new lida stret., valiasr town

**City**
tabriz

**Province**
East Azarbaijan

**Postal code**
5157844333

**Phone**
+98 41 3331 3959

**Email**
timmam.med1994@gmail.com

**Web page address**

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Tabriz 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**
Tabriz University of Medical Sciences

**Full name of responsible person**
aminreza deljooy

**Position**
medical student

**Latest degree**
A Level or less

**Other areas of specialty/work**
General Practitioner

**Street address**
No. 8 , 2nd alley.,lida street.,valiasr town

**City**
tabriz

**Province**
East Azarbaijan

**Postal code**
5157844333

**Phone**
+98 41 3331 3959

**Email**
timman.med1994@gmal.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
aminreza deljooy

**Position**
medical student

**Latest degree**
A Level or less

**Other areas of specialty/work**
General Practitioner

**Street address**
No. 8 , 2nd alley.,lida street.,valiasr town

**City**
tabriz

**Province**
East Azarbaijan

**Postal code**
5157844333

**Phone**
+98 41 3331 3959

**Email**
timman.med1994@gmal.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Tabriz University of Medical Sciences

**Full name of responsible person**
aminreza deljooy

**Position**
medical student

**Latest degree**
A Level or less
**Other areas of specialty/work**
General Practitioner
**Street address**
No. 8 , 2nd alley.,lida street.,valiasr town
**City**
tabriz
**Province**
East Azarbaijan
**Postal code**
5157844333
**Phone**
+98 41 3331 3959
**Email**
timman.med1994@gmal.com

## 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**
Yes - There is a plan to make this available
**Clinical Study Report**
Not applicable
**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
**Title and more details about the data/document**
All data is shared after the identities of the study subjects are unrecognizable
**When the data will become available and for how long**
Accessing datas starts 6 months after the results are published
**To whom data/document is available**
Researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
The relevance of the applicant's field to the study , for example, being a physician, having a justified reason for accessing the data of individuals, accessing the data only for the purpose of obtaining further information on the study, the individual's commitment not to Misuse of people's data
**From where data/document is obtainable**
nikookari hospital , cornea clinic , dr nazli taheri nikookari hospital , office of research assistance
**What processes are involved for a request to access data/document**
Authentication of the data requesting person, having a scientific and justifiable reason for accessing the data and presenting it to the hospital research assistant, specifying the amount of data access, confirming the research assistant, referring to the person in charge of the research, Dr. Nazli Taheri, Approved by Dr. Taheri
**Comments**