

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

ata mahmoodpoor

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

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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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

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