

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of recurrence and complications of pterygium surgery in the inferior rotational conjunctival autograft compared with the superior rotational conjunctival autograft in patients underwent pterygium surgery -a randomized clinical trial

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of the rate of recurrence and complications of pterygoid surgery in the surgical method with inferior rotational conjunctival autograft compared to superior rotational conjunctival autograft in patients undergoing pterygoid surgery

Last update: **2023-02-12, 1401/11/23**

Update count: **0**

Registration date

2023-02-12, 1401/11/23

Design

A controlled, parallel-group, single-blind, randomized, on 80 patients. PASS software is used for randomization.

Registrant information

Name

Mita Akbari

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 3323 6886

Email address

mitra.akbari@gums.ac.ir

Settings and conduct

The study will be conducted in the eye clinic of Amirmomenin hospital. The study will be single-blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a Pterygium larger than 3 mm at horizontal width over the cornea on Slit-lamp exam who are candidates for surgery. Non inclusion criteria: patients with previous pterygium recurrence; pseudo-ptyerygium; pregnant and breastfeeding mothers; systemic disease like diabetes and heart disease; ocular surface disease like keratitis or dry eye or conjunctivitis; prior ocular surgery within 6 months;

Recruitment status

Recruitment complete

Funding source

Intervention groups

Group A (patients who will undergo surgery with inferior rotational conjunctival autograft) and group B (patients who will undergo surgery with superior rotational conjunctival autograft)

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Clinical inflammation grading and pterygium recurrence

Scientific title

Comparison of recurrence and complications of pterygium surgery in the inferior rotational conjunctival autograft compared with the superior rotational

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160919029871N6**

Registration date: **2023-02-12, 1401/11/23**

conjunctival autograft in patients underwent pterygium surgery -a randomized clinical trial

Public title

Comparison of recurrence and complications of pterygium surgery in patients underwent pterygium surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a Pterygium larger than 3 mm at horizontal width over the cornea on Slit-lamp exam who are candidates for surgery

Exclusion criteria:

Patients with previous pterygium recurrence The size of the base of the pterygium in the limbus region is greater than 8 mm Pregnant and breastfeeding patients Patients suffering from systemic diseases such as diabetes Patients with eye surface diseases such as keratitis, conjunctivitis and severe dry eyes Patients with a background of eye surgery in the last 6 months

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

If the patients meet the inclusion criteria, they will be randomly assigned to two groups A (patients who will undergo inferior rotational conjunctival autograft) and group B (patients who will undergo surgery using superior rotational conjunctival autograft) based on random blocks. Patients will be randomly divided into 2 groups with quadruple blocks of 40 people and will be examined in a single-blind manner. Registration of participants and allocation to groups will be done by the resident. The block sequence list is kept in a sealed and sealed letter in the Ophthalmology Research Center, and after the research permission from the Ethics Committee, the envelope is opened at the beginning of the study and based on gradual referrals, the patients will be placed in A or B groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Being placed in group A or B and the type of surgery with lower conjunctival autograft or upper conjunctival autograft will not be told to the patient. (The patient will not know how to be selected in the treatment groups)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Guilan University of Medical Sciences

Street address

Shahid Siadaty St., Namju St., Rasht

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.GUMS.REC.1401.448

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

Pterygium Recurrence

Timepoint

6 Months After Surgery

Method of measurement

Clinical Examination

Secondary outcomes

1

Description

Best Corrected Visual Acuity

Timepoint

Day 1, 3, 7, 30 After Surgery

Method of measurement

Clinical Examination

2

Description

Clinical Inflammation Grading At Operation Site

Timepoint

Day 1, 3, 7, 30 After Surgery

Method of measurement

Clinical Examination

3

Description

Epithelial Defect Healing Time

Timepoint

Day 1, 3, 7, 30 After Surgery

Method of measurement

Clinical Examination

4

Description

Possible Complication of Pterygium Surgery

Timepoint

Day 1, 3, 7, 30 After Surgery

Method of measurement

Clinical Examination

Intervention groups

1

Description

Intervention group: groups A (patients who will undergo inferior rotational conjunctival autograft) Best corrected visual acuity, clinical inflammation of the pterygium surgery site, the duration of corneal epithelial defect repair, the occurrence of possible complications of pterygium surgery on the 1st, 3rd, 7th and 30th days after the operation and the recurrence of the lesion during the 6-month follow-up are checked by slit lamp. 6 months of follow-up are recorded and compared in two groups. The day after surgery, group A will be treated with topical antibiotic drugs (Chloramphenicol0.5%) and topical steroid Betamethasone 0.1%) with a dose of four times a day. The dose is reduced for two months and then stopped.

Category

Treatment - Surgery

2

Description

Control group: group B (patients who will undergo surgery using superior rotational conjunctival autograft) Best corrected visual acuity, clinical inflammation of the pterygium surgery site, the duration of corneal epithelial defect repair, the occurrence of possible complications of pterygium surgery on the 1st, 3rd, 7th and 30th days after the operation and the recurrence of the lesion during the 6-month follow-up are checked by slit lamp. 6 months of follow-up are recorded and compared in two groups. The day after surgery, group A will be treated with topical antibiotic drugs (Chloramphenicol0.5%) and

topical steroid Betamethasone 0.1%) with a dose of four times a day. The dose is reduced for two months and then stopped.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmoemenin Hospital

Full name of responsible person

Dr Mitra Akbari

Street address

Dr. Heshmati Square., Shahrivar St

City

Rasht

Province

Guilan

Postal code

41396-37459

Phone

+98 13 3323 6886

Fax

+98 13 3323 6886

Email

Mitra.akbari20@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

Street address

Namjoo Street, Shahid Siyadati Street

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan 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

Rasht
Province
Guilan
Postal code
41396-37459
Phone
+98 31 3323 6886
Email
mitra.akbari20@gmail.com

Person responsible for general inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr Mitra Akbari
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Eye Research Center, Amiralmomenin Hospital, 17
Shahrivar St, Rasht
City
Rasht
Province
Guilan
Postal code
41396-37459
Phone
+98 13 3323 6886
Email
mitra.akbari20@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Dr Mitra Akbari
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Ophthalmology
Street address
Eye Research Center, Amiralmomenin Hospital, 17
Shahrivar St, Rasht
City

Person responsible for updating data

Contact

Name of organization / entity
Guilan University of Medical Sciences
Full name of responsible person
Shila Kianmehr
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Health Service Management
Street address
Eye Research Center, Amiralmomenin Hospital, 17
Shahrivar St, Rasht
City
Rasht
Province
Guilan
Postal code
41396-37459
Phone
+98 13 3323 6886
Email
shila.kianmehr@gmail.com

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available