Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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

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

Settings and conduct
The study will be conducted in the eye clinic of Amiralmomenin 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-pterygium; 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;

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)

Main outcome variables
Clinical inflammation grading and pterygium recurrence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160919029871N6**
Registration date: **2023-02-12, 1401/11/23**
Registration timing: **prospective**

Last update: **2023-02-12, 1401/11/23**
Update count: **0**

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

Registrant information

Name
Mita Akbari

Name of organization / entity
Guilan University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

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

Scientific title
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

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
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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

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Latest degree

Subspecialist

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Person responsible for updating data

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Researcher

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Master

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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