Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

A comparative study of recurrence rate and complications between mitomycin c, interferone alpha 2b and bevasizumab after primary pterygium surgery

Protocol summary

Study aim

Comparative study of intraoperative injection of bevasizumab and interferone alpha 2b and topical application of mitomycin c , on post-operative complications and recurrence rate after primary pterygium surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 63 patients. PASS statistical software was used for randomization.

Settings and conduct

The study is performed in Khatam-al-anbia hospital in Mashhad. Patients are divided into 3 groups of 21 people. In all groups, the pterygium and subconjunctival tenon are removed and the drug is used and then conjunctival autograft is performed by the senior assistant. The subjects and evaluators are concealed in this study. concealing is done by closed envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria are the following: presence of primary pterygium at least 1 mm in size; decreased vision due to the pterygium; existence of a cylinder due to the pterygium; the patient's desire to undergo pterygium surgery; no history of pterygium surgery (primary pterygium); no history of allergy to interferon alfa 2b. exclusion criteria: active ophthalmic infection; recurrent pterygium

Intervention groups

In this study, pterygium resection is performed and for one group intraconjunctival injection of bevacizumab is given, for the second group mitomycin c is used topically during surgery and for the other group interferon alfa 2b is injected intraconjunctivally.

Main outcome variables

The recurrence rate of pterygium after primary pterygium surgery; incidence of complications after primary pterygium surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220215054028N1**
Registration date: **2022-05-17, 1401/02/27**
Registration timing: **prospective**

Last update: **2022-05-17, 1401/02/27**
Update count: **0**

Registration date

2022-05-17, 1401/02/27

Registrant information

Name

Solmaz Momtahan ghalati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-07-01, 1401/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparative study of recurrence rate and complications between mitomycin c, interferone alpha 2b and bevasizumab after primary pterygium surgery

Public title
A comparative study of recurrence rate and complications between mitomycin c, interferone alpha 2b and bevasizumab after primary pterygium surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Existence of primary pterygium at least 1 mm in size Decrease in visual acuity due to pterygium The patient's tendency for pterygium surgery Having no history of previous pterygium surgery Having no history of allergy to interferone alpha 2 B Cylinder caused by pterygium

Exclusion criteria:
Patients with recurrent pterygium Patients with no tendency for pterygium surgery Patients with active ophthalmic infection

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using statistical software PASS. To do so, the study groups (coded) and the number of patients in each group will be entered into the software and a random sequence of the patients will be generated. The sequences will be inserted into some thick envelopes in the same order as they were generated by a person who is not aware of the study so that the contents of the envelopes are not visible. Then, an envelope (in the order of the sequence generated) will be opened for each patient admitted to the study and the patient will be grouped into one of the three study groups based on the content of the envelope. All steps of sequencing and the process of grouping the patients will be done by someone who is not aware of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The sequences will be inserted into some thick envelopes in the same order as they were generated by a person who is not aware of the study so that the contents of the envelopes are not visible. Then, an envelope (in the order of the sequence generated) will be opened for each patient admitted to the study and the patient will be grouped into one of the three study groups based on the content of the envelope. All steps of sequencing and the process of grouping the patients will be done by someone who is not aware of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Education department, Khatam-al-anbia Hospital, Gharani 41, Gharani Blvd.

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Mashhad

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Razavi Khorasan

Postal code
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Approval date
2022-02-14, 1400/11/25

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.769

Health conditions studied

1

Description of health condition studied
Primary pterygium

ICD-10 code
H11.0

ICD-10 code description
Pterygium of eye

Primary outcomes

1

Description
Pterygium recurrence rate after primary pterygium surgery

Timepoint
At the beginning of the study, after 48 hours, one week, one month, 6 months and then 1 year after the operation

Method of measurement
Slit lamp

2

Description
Complication rate after primary pterygium surgery

Timepoint
At the beginning of the study, after 48 hours, one week, one month, 6 months and then 1 year after the operation
Method of measurement
Slit lamp

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: after pterygium removal, 1.25 mg bevacizumab is injected into the recipient conjunctiva 5 mm far from the free edge of the recipient area in the superior, inferior and nasal areas, and then free conjunctival autograft is performed.
Category
Treatment - Drugs

2

Description
Intervention group: after removing the pterygium, 3 million units of interferon alfa 2b is injected into the recipient conjunctiva at 5 mm far from the free edge of the graft receptor area in the superior, inferior and nasal areas, and then free conjunctival autograft is performed.
Category
Treatment - Drugs

3

Description
Intervention group: after removal of the pterygium, the area under the pterygium is covered with a sponge soaked in mitomycin c for 90 seconds, then washed and a free conjunctival autograft is performed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
بیمارستان چشم پزشکی خاتم الانبیا مشهد
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour Mobarhan
Street address
Vice Chancellor for Research and Technology, third floor, University of Medical Sciences, next to Hoveyzeh Cinema, University Street, Mashhad, Khorasan Razavi
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Solmaz Momtahan ghalati
Position
Resident of ophthalmology
Latest degree
Medical doctor
Other areas of specialty/work

Ophthalmology

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No 3, Kolahdouz 44, Kolahdouz avenu, Mashhad town

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

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