

# 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)

##### Phone

+98 938 094 6737

##### Email address

momtahens981@mums.ac.ir

##### 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.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9190960919

#### 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**

Solmaz Momtahan ghalati

**Street address**

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

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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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GhayourM@mums.ac.ir

**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

**Street address**

No 3, Kolahdouz 44, Kolahdouz avenu, Mashhad town

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Solmaz Momtahan ghalati

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## Person responsible for updating data

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**Name of organization / entity**

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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