

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparison of the effect of interferon alfa 2 b (IFN- $\alpha$ 2b) drops with mitomycin c during surgery on pterygium recurrence in pterygium surgery by Rotational conjunctival autograft method

#### Protocol summary

##### Study aim

To determine the impact of topical interferon alfa2b drops on inflammation, recurrence and complications of pterygium surgery

##### Design

Patients with a Pterygium larger than 3 mm at horizontal width on the cornea on Slit-lamp exam candidates for surgery. Patients are included and assigned randomly into 2 groups. One group receiving topical drops of corticosteroids, antibiotic and interferon alfa2b and the other receiving topical drops of corticosteroids and antibiotic and mitomycin during surgery. On post operative day 1, 3, 7, 30, 90 and 6 months after surgery patients corrected visual acuity, clinical inflammation grading, time for epithelial defect to repair and complications of surgery and recurrence of pterygium will be examined and compared in these groups

##### Settings and conduct

The study will be conducted in the eye clinic of Amiralmomenin hospital. The study will be single-blind and patients will not be informed of the addition of interferon alfa2b drop

##### 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; hypersensitivity to interferon alfa2b

##### Intervention groups

Patients who were included were assigned randomly through block randomization using blocks of size 4. Group A: Patients receiving topical drops of corticosteroids, antibiotic and interferon alfa2b (without

received mitomycin during surgery). Group B: Patients receiving topical drops of corticosteroids and antibiotic and mitomycin during surgery.

##### Main outcome variables

Clinical inflammation grading and pterygium recurrence

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160919029871N5**

Registration date: **2021-12-26, 1400/10/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-26, 1400/10/05**

Update count: **0**

##### Registration date

2021-12-26, 1400/10/05

##### 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

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-12-22, 1401/10/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of interferon alfa 2 b (IFN- $\alpha$ 2b) drops with mitomycin c during surgery on pterygium recurrence in pterygium surgery by Rotational conjunctival autograft method

**Public title**  
Comparison of the effect of interferon alfa 2 b (IFN- $\alpha$ 2b) drops with mitomycin c during surgery on pterygium recurrence in 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, 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  
Hypersensitivity to interferon alfa 2 b.

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: 58

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients with random allocation software version 2 based on quadruple random blocks (with a choice of 15 quadruple random blocks), into two groups A (patients who, in addition to receiving corticosteroid and antibiotics, eye drops) They will also receive alpha interferon 2b, but without the use of mitomycin during surgery) and group B (patients who receive only eye drops of corticosteroids and antibiotics and mitomycin during surgery) will be randomly substituted. The list of block sequences is kept in a sealed letter at the Ophthalmology Research Center, and after permission from the ethics committee to conduct the study, the envelope is opened at the beginning of the study and patients are placed in group A or B based on gradual referrals.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**  
The addition of interferon alfa 2 b drop is not explained to the patients

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
کمیته اخلاق دانشگاه علوم پزشکی گیلان  
**Street address**  
Shahid Siadaty St., Namju St., Rasht  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
41446-66949

**Approval date**  
2021-11-24, 1400/09/03

**Ethics committee reference number**  
IR.GUMS.REC.1400.411

## 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**  
Clinical inflammation grading and pterygium recurrence

**Timepoint**  
Day 1, 3, 7, 30, 90 and 6 months after surgery

**Method of measurement**  
Clinical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group: Aside from the topical Bethamethasone and Antibiotic drops the intervention group will receive topical drops of interferon alfa 2 b (IFN- $\alpha$ 2b) drops for 3 months.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Control group: Patients receiving topical Corticosteroids and Antibiotic drops and mitomycin during surgery

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amiralmomenin Hospital

##### Full name of responsible person

Mitra Akbari

##### 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

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Naghipour

##### Street address

Shahid Siadaty St, Namju St, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41446-66949

##### Phone

+98 13 3333 0862

##### Email

research@gums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Rasht 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

Rasht 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

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rasht 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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**Postal code**

41396-37459

**Phone**

+98 13 3323 6886

**Email**

shila.kianmehr@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Rasht 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**

**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