

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of interferon alfa 2 b (IFN- α 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

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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-α2b) 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-α2b) 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- α 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

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41396-37459

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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

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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

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Person responsible for updating data

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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