

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Intralesional administration of interferon alfa 2-b in treatment of pterygium

Protocol summary

Study aim

Intralesional administration of interferon alfa 2-b in treatment of pterygium

Design

A randomized, single blinded, clinical trial with a parallel group design of 60 patients, enrolled between February 2020 and February 2021

Settings and conduct

The current study is a single blinded clinical trial conducted at Al-Zahra Hospital in Zahedan. Patients with pterygium with at least 1 mm of corneal involvement will be included in the study. Patients will be divided into each of the study groups based on the block randomization method. In 30 patients, in intervention group, we will inject interferon alfa-2b in the pterygium base near the Limbus area and in 30 other patients (Control group), sterile physiological saline solution will be administered as placebo. In all cases, chloramphenicol 0.5% will be administered 4 times in first 24 hours after beginning of treatment. Patients will be examined again after 48 hours, one week, and then monthly for 6 months after injection, and will be evaluated by pterygium size, conjunctivitis, and photophobia.

Participants/Inclusion and exclusion criteria

Patients referring to Al-Zahra Ophthalmology hospital in Zahedan
Inclusion criteria: Patients with pure Pterygium that involve at least 1mm of cornea based on clinical diagnosis
Exclusion criteria: Any eye pathology other than pterygium

Intervention groups

Patients will be divided into two groups randomly, in Intervention group 0.1 ml interferon α -2b (IFN- α -2b) will be injected in the pterygium base. then chloramphenicol will be administered QID in first 24 hours after beginning of treatment. In Control group 0.1 ml Sterile Physiological Serum will be injected in the pterygium base. then chloramphenicol 0.5% will be administered QID in first 24 hours after beginning of treatment.

Main outcome variables

Pterygium size: Photophobia: Pterygium Hyperemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120817010617N5**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

morteza Sedaghat Kia

Name of organization / entity

zaums

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 9540

Email address

morimedico@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Intralesional administration of interferon alfa 2-b in treatment of pterygium

Public title
Effect of administration of interferon alfa 2-b in treatment of pterygium

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with pure Pterygium that involve at least 1mm cornea based on clinical diagnosis

Exclusion criteria:
Any eye pathology other than pterygium

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with blocks of 10. Considering the sample size of 60, 6 blocks will be selected; in each block there will be equal numbers of cards for each group. By selecting each block, 10 patients in each group will be selected.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients will be randomly assigned to one of the two groups receiving interferon α -2b or Sterile Physiological Serum. The administration of medication or serum is the same in both groups, and patients will be unaware of the group assignment. therefore this study will be a single blinded clinical trial study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1
Ethics committee

Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Dr.Hesabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2018-09-23, 1397/07/01
Ethics committee reference number
Ir.ZAUMS.REC.1398.447

Health conditions studied

1
Description of health condition studied
pterygium of eye
ICD-10 code
H11.0
ICD-10 code description
Pterygium of eye

Primary outcomes

1
Description
Pterygium size
Timepoint
Patients will be examined after 48 hours, one week, and then monthly for 6 months after injection.
Method of measurement
Based on slit lamp examination

2
Description
Photophobia
Timepoint
Patients will be examined after 48 hours, one week, and then monthly for 6 months after injection.
Method of measurement
Based on slit lamp examination

3
Description
Pterygium Hyperemia
Timepoint
Patients will be examined after 48 hours, one week, and then monthly for 6 months after injection.
Method of measurement
slit lamp examination

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: 0.1 ml interferon α -2b (IFN- α -2b) IntronA, Schering Plough, Kenilworth, NJ1 million units/mL) will be injected in the pterygium base near the Limbus area. then chloramphenicol 0.5% will be administered QID in first 24 hours after beginning of treatment.

Category

Treatment - Drugs

2

Description

Control group: 0.1 ml Sterile Physiological Serum will be injected in the pterygium base near the Limbus area. then chloramphenicol 0.5% will be administered QID in first 24 hours after beginning of treatment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Eye hospital

Full name of responsible person

Meisam Sargazi

Street address

Shahid Motahar Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

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9816737789

Phone

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Email

Meisam.sargazi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nour Mohammad Bakhshani

Street address

Dr Hesabi Sq.

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Email

zaums.research@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Meisam Sargazi

Position

Ophthalmology resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Shahid Motahar Blvd, Al-Zahra Eye hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Arish

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Meisam Sargazi

Position

Ophthalmology resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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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