

# 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  $\alpha$ -2b (IFN- $\alpha$ -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  $\alpha$ -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  $\alpha$ -2b (IFN- $\alpha$ -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

#### Postal code

9816737789

#### Phone

+98 54 3321 9915

#### 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.

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

9816743463

#### Phone

+98 54 3329 5796

#### 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

#### City

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#### Province

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#### Phone

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#### Email

Meisam.sargazi@gmail.com

## 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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Arish.mohammed@gmail.com

**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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**Email**

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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