

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The efficacy of topical interferon alpha-2b in primary and recurrent pterygium

Protocol summary

Study aim

The efficacy of topical interferon alpha-2b in primary and recurrent pterygium

Design

The data collection tool was a two-part questionnaire. The first part contains patient's identification and demographic information. The second part of questionnaire contains history and ophthalmic examination. Ophthalmic examination (keratometry, size, grade, BCVA, UCVA, refraction) was done for all patients 4 times: before the first subconjunctival injection, the end of first month, third month, sixth month.

Settings and conduct

The study were performed on patients with Pterygium attending to Ophthalmology clinic of Baqiyatallah hospital, Tehran, Iran; whose disease has been confirmed by an ophthalmologist. Patients were subconjunctivalally injected with interferon alpha-2b with 3million / ml every one month for two occasions. At the same time, a topical drop of interferon alpha-2b with a concentration of 1 million unit / ml for patients was initiated. The duration of use of this drop was three months, with the first month every 6 hours, the second month every 8 hours, and the third month every 12 hours.

Participants/Inclusion and exclusion criteria

The inclusion criteria were defined as: Any patients with primary pterygium; either unilaterally or bilaterally, who diagnosed by an ophthalmologist. Exclusion criteria: -Use of any local ophthalmic drug -Patients with History of Refractive Surgery -History of any eye diseases other than refractive disorders -Pregnant or lactating women

Intervention groups

Subconjunctival injections of 3 million/ml Interferon alpha-2b was done for all patients two times: the first injection was done in the first day and second injection was performed at the end of first month. IFN α 2b. Also IFN α 2b 1 million/ml Topical eye-drops was given to all patients for three month.

Main outcome variables

The efficacy of topical interferon alpha-2b in primary and recurrent pterygium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044463N1**

Registration date: **2019-12-09, 1398/09/18**

Registration timing: **retrospective**

Last update: **2019-12-09, 1398/09/18**

Update count: **0**

Registration date

2019-12-09, 1398/09/18

Registrant information

Name

Ahmad zarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4254 0608

Email address

ahmadzare1373@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2018-02-01, 1396/11/12

Actual recruitment start date

2016-09-01, 1395/06/11

Actual recruitment end date

2018-02-01, 1396/11/12
Trial completion date
2018-06-01, 1397/03/11

Scientific title
The efficacy of topical interferon alpha-2b in primary and recurrent pterygium

Public title
The efficacy of topical interferon alpha-2b in pterygium

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Any patients with primary or recurrent pterygium; either unilaterally or bilaterally, who was diagnosed by an ophthalmologist

Exclusion criteria:

Use of any topical ophthalmic drug in previous six months
Patients with allergy to interferon alpha-2b
Patients with History of Refractive Surgery
History of any eye diseases other than refractive errors and pterygium
Pregnant or lactating women

Age
From **19 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **18**
Actual sample size reached: **18**
More than 1 sample in each individual
Actual sample size in each individual: **2**
18 eyes (16 patients)

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of baqiyatallah University of Medical Sciences

Street address

Iranshahr Ave., opposite Artists' Park - Mofatteh
Dormitory - Room 400

City
tehran

Province
Tehran

Postal code
1583737811

Approval date
2017-12-11, 1396/09/20

Ethics committee reference number

این کد در سال 1396 اخذ شده است و به lr.bmsu.rec.1396.471
همین دلیل است که در سامانه ملی اخلاق در پژوهش های زیست
موجود نیست. تصویر ethics.research.ac.ir پزشکی به آدرس
گواهی تاییدیه اخلاق به همراه شماره تراپال به آدرس ایمیل
admin@irct.ir

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

pterygium grade

Timepoint

1- Baseline (before injection) 2- 1st month 2- 2nd month
3- 6th month

Method of measurement

Based on the degree of visibility of the epithelial vessels
by an ophthalmologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: interferon alpha 2b (In this study,
there was only one intervention group: There was no
control group in this study: Comparison between pre and
post intervention was performed in the same group.)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Ophthalmology Clinic

Full name of responsible person

Esmail Shabaninezhad

Street address

Mulla Sadra Street, Sheikh Bahai Intersection,
Baqiyatallah Clinic

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ahmadzareei1373@gmail.com

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

gholamhossein alishiri

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Mulla Sadra Street, Sheikh Bahai Intersection,
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<https://www.bmsu.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Esmail Shabaninezhad

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Esmail Shabaninezhad

Position

resident

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

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