

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Assessment of subconjunctival bevacizumab effect on the postoperative healing course and recurrence of excised primary pterygium in patients referring to ophthalmology clinics

Protocol summary

Summary

Purpose: assessment of subconjunctival bevacizumab effect on the postoperative healing course and recurrence of excised primary pterygium. Design: randomized, double blind, placebo controlled, unicentric. Population: cases were selected from the patients referring to the ophthalmology clinics affiliated to Shiraz University of Medical Sciences, wanting removal of pterygium. Exclusion criteria: glaucoma, any previous limbal or pterygium surgery, obvious reflux from puncta, untreated diabetics, autoimmune disease, pregnant patients, ocular infection. Study size:32, after selecting the patients, pre-op exam was done and if met the criteria of study, after taking informed consent, were randomized into 2 groups, using random number tables. The group one (G1) had pterygium excision and rotational conjunctival flap with a total of 7.5 mg adjunctive subconjunctival bevacizumab (5mg/0.2ml on the surgery day and 2.5 mg/0.1 ml on the 4th day after surgery). The group 2 (G2) received 0.2ml Balanced Salt Solution (BSS) at the end of the surgery. Postoperatively, patients were examined at 1st day, 1st week, and 1st month, 3rd month, 6th and 12th month. In each exams, corneal epithelial defect, conjunctival erythema, lacrimation, photophobia, refraction, intraocular pressure are evaluated. Primary outcome measure in 2 groups is recurrence of pterygium.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138805192326N1**
Registration date: **2010-09-28, 1389/07/06**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-28, 1389/07/06

Registrant information

Name

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Name of organization / entity

Department of ophthalmology, Shiraz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences

Expected recruitment start date

2009-08-15, 1388/05/24

Expected recruitment end date

2010-09-01, 1389/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of subconjunctival bevacizumab effect on the postoperative healing course and recurrence of excised primary pterygium in patients referring to ophthalmology clinics

Public title

Assessment of subconjunctival bevacizumab effect on the postoperative healing course and recurrence of excised pterygium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the patients with primary pterygium referring to the ophthalmology clinics, affiliated to Shiraz University of Medical Sciences, that want pterygium removal. Exclusion criteria: glaucoma, regurgitation from lacrimal punctum (any indication of nasolacrimal obstruction), patients that seems not coming for follow-up exams during study, not treated diabetic patients, autoimmune diseases, pregnant patients, patients with ocular surface diseases or infections, two headed pterygium, previous limbal surgery, previous pterygial surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences ethics committee

Street address

7th floor, Shiraz university of medical sciences, Zand St.

City

Shiraz

Postal code

Approval date

1389-05-21, 769/01/-303

Ethics committee reference number

ct-89-1527

Health conditions studied

1

Description of health condition studied

pterygium

ICD-10 code

H18.4

ICD-10 code description

corneal degeneration

Primary outcomes

1

Description

recurrence of pterygium

Timepoint

1 month, 3 months, 6 months after operation

Method of measurement

Slit lamp examination and measuring the size of recurrent pterygial tissue on cornea

Secondary outcomes

1

Description

healing of the surgical wound

Timepoint

1 week, 1 month

Method of measurement

observing erythema, subconjunctival hemorrhage, corneal epithelial defect, tearing, photophobia of the patients

Intervention groups

1

Description

Intervention in cases: after excision of pterygium and rotational conjunctival flap, 5 mg (0.2ml) of bevacizumab injected subconjunctivally in inferior fornix, and in the first post operative week additional 2.5mg of bevacizumab again injected in subconjunctival area in inferior fornix.

Category

Treatment - Drugs

2

Description

Intervention in controls: after excision of pterygium and rotational conjunctival flap, 0.2 ml of balanced salt solution, injected subconjunctivally in inferior fornix.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poostchi eye clinic

Full name of responsible person

Street address

City

Shiraz

2

Recruitment center

Name of recruitment center

Motahhari eye clinic

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellery of Research Affairs of Shiraz
University of Medical Sciences

Full name of responsible person

Mohammad Hossein Dabbaghmanesh

Street address

7th floor, central building of Shiraz university of
medical sciences, Zand Ave.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellery of Research Affairs of Shiraz University
of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz university of medical sciences

Full name of responsible person

Mohammad Banifatemi

Position

Ophthalmology resident

Other areas of specialty/work

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty