

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

To assess the efficacy of sub-conjunctival Bevacizumab (Avastin) injection in treatment of primary fleshy pterygium (based on TAN grading) in patients with bilateral primary fleshy pterygium in comparison with sham injection

Protocol summary

Summary

Objective: To assess the efficacy and role of sub-conjunctival Bevacizumab injection in treatment of primary fleshy pterygium. Design: The study population: Patients with bilateral primary fleshy pterygium. Sample size: Forty eyes of twenty patients. Inclusion criteria: Patients with 20 to 70 years old, with primary bilateral fleshy pterygium invading between 1 to 4 mm into the cornea. Exclusion criteria: Any evidence of cancer or other ocular diseases except refraction errors (including anterior segment and posterior segment), diabetic patients and pregnancy. Setting and conduct: A complete eye evaluation will be performed for each patient. This includes visual-acuity determination, applanation tonometry, slit lamp examination, keratometry, and anterior segment photography. Some clinical symptoms (tingling, itching, redness, epiphora) will be noted. Avastin will be injected in subconjunctival area of pterygium body. Patients will be followed up after a week, one month, three months and six months. A complete ophthalmologic evaluation will be performed for each follow-up. Any complications will be noted. Anterior segment photography will be done for every follow-up. Interventions: Using a 1-ml syringe with 30-gauge needle, 2.5 mg (0.1 ml) of bevacizumab will be injected to the subconjunctival area of pterygium body. Sham injection will be done for the other eye of the same patient (control group). Main outcome measures: TAN grading, mean pterygium size, mean surface area of pterygium, hyperemia, photophobia, keratometry, best corrected visual acuity and clinical symptoms (tingling, itching, redness, epiphora).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014092819319N1**

Registration date: **2015-01-24, 1393/11/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-24, 1393/11/04

Registrant information

Name

Alireza Haghi

Name of organization / entity

Iran University of Medical Science

Country

Iran (Islamic Republic of)

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Email address

alireza_haghi1389@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Science

Expected recruitment start date

2013-07-23, 1392/05/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To assess the efficacy of sub-conjunctival Bevacizumab (Avastin) injection in treatment of primary fleshy pterygium (based on TAN grading) in patients with bilateral primary fleshy pterygium in comparison with sham injection

Public title

To assess the efficacy of Avastin injection in treatment of pterygium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with 20 to 70 years old, with primary bilateral fleshy pterygium invading between 1 to 4 mm into the cornea. Exclusion criteria: Any evidence of cancer or other ocular diseases except refraction errors (including anterior segment and posterior segment), diabetic patients and pregnancy.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Double-blind trial (neither participants nor researchers)

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Science

Street address

No. 21, Damascus Street, Palestine Avenue, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2013-07-20, 1392/04/29

Ethics committee reference number

130/762/92/5

Health conditions studied**1****Description of health condition studied**

pterygium

ICD-10 code

H11.0

ICD-10 code description

PTERYGIUM

Primary outcomes**1****Description**

TAN grading

Timepoint

After one month, three months and six months .

Method of measurement

based on the visibility of the underlying episcleral blood vessels in slit-lamp examination (questionnaire)

2**Description**

mean pterygium size

Timepoint

After one month, three months and six months.

Method of measurement

Millimeter(By slit-lamp)

3**Description**

photophobia

Timepoint

After one month, three months and six months.

Method of measurement

Questionnaire

4**Description**

mean surface area of pterygium

Timepoint

After one month, three months and six months.

Method of measurement

Square millimeters(By slit-lamp)

5**Description**

Hyperemia

Timepoint

After one month, three months and six months.

Method of measurement

Questionnaire

6

Description

keratometry

Timepoint

After one month and six months.

Method of measurement

By keratometer device

7

Description

Best corrected visual acuity

Timepoint

After one month, three months and six months.

Method of measurement

Snellen -E-chart

8

Description

Clinical symptoms (tingling, itching, redness, epiphora)

Timepoint

After one week, one month, three months and six months.

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Complications for example;infection and hemorrhage

Timepoint

After one week, one month, three months and six months.

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention 1: Using a 1-ml syringe with 30-gauge needle, 2.5 mg (0.1 ml) of bevacizumab will be injected to the subconjunctival area of pterygium body only once.

Category

Treatment - Drugs

2

Description

The intervention No. 2: Sham injection will be done for the other eye of the same patient only once.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-E-Rasoul Hospital

Full name of responsible person

Alireza Haghi

Street address

1th Floor, Department of Ophthalmolgy, Hazrat-E-Rasoul Hospital, Niayesh St., Sattarkahn Ave.

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Science

Full name of responsible person

Seyed Ali Javad Moosavi

Street address

7th Floor, Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Niayesh St., Sattarkahn Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Science

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

Iran University of Medical Science

Full name of responsible person

Alireza Haghi

Position

Resident of Ophthalmology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty