

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of intravitreal injection of bevacizumab and triamcinolone acetonide in the treatment of uveitic macular edema

#### Protocol summary

##### Summary

Macular edema is the most common cause of visual loss in uveitis which occurs in approximately 33% of the uveitic eyes. VEGF by its angiogenic character, ability to create fenestration between the endothelial cells, formation of vesicular organelles and trans-cellular gaps plays its role in vascular leakage and formation of macular edema. Today, there is no consistent protocol for management of uveitic macular edema. In the present study, we aim to compare the long term effect of bevacizumab versus intravitreal triamcinolone in management of uveitic macular edema. For this purpose eyes from patients with inactive uveitis, who had visual loss due to macular edema and not responding to topical medication such as steroid, will enrolled in this study. The eyes will be randomly divided into two groups; the 1st group will receive 0.05 ml (1.25 mg) intravitreal Bevacizumab (IVB) and the 2nd group 0.05ml (2mg) Triamcinolone acetonide. Outcome measures will best corrected visual acuity in the form of logarithm of the minimum angle of resolution (log MAR) and central macular thickness by means of OCT at 3, 6, and 12 months after injection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016100930224N1**

Registration date: **2016-11-27, 1395/09/07**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-11-27, 1395/09/07

##### Registrant information

##### Name

Behzad Khademi

##### Name of organization / entity

Shiraz University of medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3626 2531

##### Email address

khademi.behzad@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-11-20, 1395/08/30

##### Expected recruitment end date

2018-05-20, 1397/02/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of intravitreal injection of bevacizumab and triamcinolone acetonide in the treatment of uveitic macular edema

##### Public title

Comparison of intravitreal anti-VEGF drug and steroid in the treatment of uveitic macular edema

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with inactive uveitis, according to sun group classification, who had visual loss due to macular edema (diagnosed by optical coherence

tomography (OCT)) and not responding to topical medication such as steroid. Exclusion criteria included any other ophthalmic disease that causes macular edema (e.g. diabetes, venous occlusive diseases); any intraocular surgery within 3 months of injection; media opacity that hinders assessment of macula by OCT, prior vitrectomy; Glaucoma; ocular hypertension and monocularly.

**Age**

From **9 years** old to **47 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences central building,  
Zand BLVD, Shiraz, Iran

**City**

Shiraz

**Postal code****Approval date**

2013-10-26, 1392/08/04

**Ethics committee reference number**

91-01-01-4883

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

Macular edema in uveitic eyes

**ICD-10 code**

H30.9

**ICD-10 code description**

Chorioretinal inflammation, unspecified

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

Macular thickness

**Timepoint**

3, 6 and 12 months after injection of drug

**Method of measurement**

Optical Coherence Tomography

**Secondary outcomes****1****Description**

Visual acuity

**Timepoint**

3, 6 and 12 months after injection

**Method of measurement**

Snellen chart

**Intervention groups****1****Description**

The eyes will randomly divided into two groups; the 1st group will receive 0.05 ml (1.25 mg) intravitreal Bevacizumab (IVB).

**Category**

Treatment - Drugs

**2****Description**

The eyes will randomly divided into two groups; the 2nd group will receive 0.05ml (2mg) Triamcinolone acetonide intravitreally.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Khalili Hospital

**Full name of responsible person**

Dr. Mansour Rahimi

**Street address**

Shiraz, Khalili Street, Khalili Hospital

**City**

Shiraz

**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Sayed Basir Hashemi

**Street address**

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

**City**

Shiraz

**Grant name**

پایان نامه دستیار

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, 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**

Dr. Mansour Rahimi

**Position**

Ophthalmologist, retina and vitreous fellowship

**Other areas of specialty/work****Street address**

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

**City**

Shiraz

**Postal code**

7134997446

**Phone**

+98 71 3481 4336

**Fax****Email**

mrahimi@ucla.edu

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mansour Rahimi

**Position**

Ophthalmologist, Retina and Vitreous fellowship

**Other areas of specialty/work****Street address**

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

**City**

Shiraz

**Postal code**

7134997446

**Phone**

+98 71 3481 4336

**Fax****Email**

mrahimi@ucla.edu

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Behzad Khademi

**Position**

Ophthalmologist

**Other areas of specialty/work****Street address**

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz, Iran

**City**

Shiraz

**Postal code****Phone**

+98 71 3481 4336

**Fax****Email**

khademi.behzad@gmail.com

**Web page address**

### 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*