

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Intravitreal bevacizumab(Avastin) for macular edema secondary to uveitis: 1 year results of a prospective pilot study

#### Protocol summary

##### Summary

Uveitis is inflammation of uveal tract and adjacent structures. Cystoid macular edema (CME) is a common cause of visual loss in uveitic eyes. Although the pathogenesis of CME in uveitis is not understood completely, Vascular Endothelial Growth Factors (VEGF) are pro-inflammatory cytokines that mediate active intraocular inflammation and is suggested as cause of CME. Bevacizumab (Avastin) is a recombinant humanized anti-VEGF monoclonal antibody approved by the Food and Drug Administration for the treatment of metastatic colorectal cancer. Recently, preliminary studies have indicated desirable effects of intravitreal injection of bevacizumab (IVB) for uveitic CME without significant ocular complications. In this study, we are going to evaluate the long-term outcome of intravitreal bevacizumab in the treatment of refractory uveitic macular edema. In a prospective clinical trial consecutive 30 patients with uveitis and CME were referred to Motahhari uveitis clinic will be enroll in the study. None of the patients will have a systemic or an ocular disease other than the one causing uveitis. Patients with history of other diseases causing macular edema (such as diabetes mellitus and retinal vein occlusions) will be excluded from the study. All of the patients should have decreased vision due to Cystoid Macular Edema (CME), diagnosed by clinic and confirmed by Optical Coherence Tomography, and non-responding to conventional topical medication such as corticosteroids. so we will determine best corrected visual acuity with logMAR and central macular thickness(CMT) by SD- OCT of macula, then will inject 1.25 mg intravitreal bevacizumab. we will determine visual acuity and OCT of macula after injection to see any improvement. All selected patients will be under follow up 1month, 3months, 6months and then 1 year after injection by best corrected visual acuity and SD-OCT. purpose: To determine the long-term safety and efficacy of intravitreal bevacizumab for the treatment of macular edema secondary to uveitis According to sex

and age and type of uveitis and best corrected visual acuity (BCVA) gain and optical coherence tomography (OCT) measurements

#### General information

##### Acronym

CME : cystoid macular edema

##### IRCT registration information

IRCT registration number: **IRCT138902113846N1**

Registration date: **2014-06-07, 1393/03/17**

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

Last update:

Update count: **0**

##### Registration date

2014-06-07, 1393/03/17

##### Registrant information

##### Name

Mansour Rahimi

##### Name of organization / entity

SUMS

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71116279373

##### Email address

mrahimi@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-08-23, 1392/06/01

##### Expected recruitment end date

2014-08-23, 1393/06/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Intravitreal bevacizumab(Avastin) for macular edema secondary to uveitis: 1 year results of a prospective pilot study

**Public title**  
Intravitreal bevacizumab(Avastin) for macular edema secondary to uveitis: 1 year results of a prospective pilot study

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
In a prospective clinical trial consecutive 30 patients with uveitis and CME will be enroll in the study. None of the patients will have a systemic or an ocular disease other than the one causing uveitis. Patients with history of other diseases causing macular edema (such as diabetes mellitus and retinal vein occlusions) will be excluded from the study. All of the patients should have decreased vision due to Cystoid Macular Edema (CME),

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**Randomization (investigator's opinion)**  
N/A

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Shiraz University of Medical Sciences

**Street address**  
Shiraz University of Medical Sciences , Zand Street

**City**  
Shiraz

**Postal code**

**Approval date**  
2013-11-20, 1392/08/29

**Ethics committee reference number**  
ct-p-92-4883

## Health conditions studied

### 1

**Description of health condition studied**

Macular edema secondary to uveitis

**ICD-10 code**  
H35.8

**ICD-10 code description**  
Other specified retinal disorders

## Primary outcomes

### 1

**Description**

Best corrected visual acuity

**Timepoint**

Before injection and 1, 3, 6 and 12 months after injection

**Method of measurement**

Standard snellen chart and log mar

### 2

**Description**

Central macular thickness

**Timepoint**

Before injection and 1, 3, 6 and 12 months after injection

**Method of measurement**

SD-OCT

## Secondary outcomes

### 1

**Description**

Complication of intravitreal injection of bevacizumab

**Timepoint**

During 1 year after injection

**Method of measurement**

Routine physical examination

## Intervention groups

### 1

**Description**

intra vitreal injection of bevacizomab(avastin)

**Category**

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Uveitis Clinic of Motahari Polyclinic  
**Full name of responsible person**  
Rahimi Mansour MD  
**Street address**  
Motahari Polyclinic, Namazi square  
**City**  
Shiraz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Gholam Reza Hatam  
**Street address**  
Shiraz University of Medical Sciences , Zand Street  
**City**  
Shiraz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
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. Hooman Razmi  
**Position**  
MD, resident of ophthalmology  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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hooman2482@gmail.com  
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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*