

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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)

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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

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Position

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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