

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)

Phone

+98 71116279373

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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

Dr. Hooman Razmi

Position

MD, resident of ophthalmology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Person responsible for updating data

Contact

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Shiraz University of Medical Sciences

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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