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 Bevacizvmab (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 monocularity.

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 Bevacizvmab (IVB).

Category
Treatment - Drugs

2

Description
The eyes will randomly divided into two groups; the 2nd group will recive 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 دستیاری

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 vitrous 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 Vitrous fellowship

Other areas of specialty/work

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

City
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Postal code
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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