

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of visual acuity and macular thickness in patients with macular edema caused by branch retinal vein occlusion treated with intravitral avastin and intravitral avastin and tissue plasminogen activator

Protocol summary

Summary

50 patients with macular edema caused by branch retinal vein occlusion will be studied. They will enter the study if their macular edema would not recover in 3 months since the disease initiation, their visual acuity is less than 20/40 and the macular thickness is more than 250 micrometer in their optical coherence tomography. They will be excluded from the study in the case of having other systemic disease, previous history of vitrectomy or posterior vitreous detachment. The patients will be divided into two groups each including 25 patients. The first group will get only Avastin, the second group will get both Avastin and tissue plasminogen activator intravitally. The patient's visual acuity and macular thickness will be evaluated in the first, third and sixth months after injection.

General information

Acronym

BRVO -Branch Retinal Vein Occlusion

IRCT registration information

IRCT registration number: **IRCT2014072618596N1**

Registration date: **2014-08-21, 1393/05/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-21, 1393/05/30

Registrant information

Name

Karim Sadeghi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-02-03, 1392/11/14

Expected recruitment end date

2014-08-05, 1393/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of visual acuity and macular thickness in patients with macular edema caused by branch retinal vein occlusion treated with intravitral avastin and intravitral avastin and tissue plasminogen activator

Public title

Comparison of visual acuity and macular thickness in patients with macular edema caused by branch retinal vein occlusion treated with intravitral avastin and intravitral avastin and tissue plasminogen activator

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Having the diagnosis of BRVO. 2) Slit

lamp examination: macular edema. 3) Snellen visual acuity: vision worse than 20/40. 4) Optical coherence tomography finding: central macular thickness of 250µm and over on. Exclusion: 1) BRVO associated with vitreous hemorrhage. 2) previous treatment with laser photocoagulation. 3) History of previous vitrectomy. 4) Intraocular pressure more than 21 mmHg. 5) Uncontrolled diabetes. 6) Systemic blood pressure. 7) Uveitis. 8) Any evidence of posterior vitreous detachment.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tabriz University of Medical Sciences

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Central Department No2, Tabriz University of Medical Sciences, Golgasht st

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5165665931

Approval date

2014-01-04, 1392/10/14

Ethics committee reference number

92185

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

Retinal vein occlusion

ICD-10 code

H34.8

ICD-10 code description

Retinal vein occlusion_partial

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

Visual acuity

Timepoint

Before intervention, one month, 3 months, 6 months after intervention

Method of measurement

Snellen chart

2**Description**

Central macular thickness

Timepoint

Before intervention, one month, 3 months, 6 months after intervention

Method of measurement

Optical Coherence tomography

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

Endophthalmitis

Timepoint

1, 3 and 6 month after intervention

Method of measurement

clinical

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

For the 25 patients Intravitreal Avastin and Tissue Plasminogen Activator will be injected

Category

Treatment - Surgery

2**Description**

For the 25 patients Intravitreal Avastin will be injected

Category

Treatment - Surgery

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

Nikookari Eye Hospital

Full name of responsible person

Dr.Sadegi Karim

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for Research and Technology, Tabriz University of Medical Science

Full name of responsible person

Dr. Shakuri Seyyed Kazem

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Chancellor of Research and Technology, Third Floor, Central Department No.2, Tabriz University of Medical sciences, Golgasht st

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

Yes

Title of funding source

Vice chancellor for Research and Technology, Tabriz University of Medical Science

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**

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Full name of responsible person

Dr.Sadegi Karim

Position

Associate professor of Ophthalmology- Vitreoretinal Fellowship

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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