Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of visual acuity and macular thickness in patients with macular edema cuased 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 vitrous 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 intravitrally. 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
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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 cuased 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 cuased 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 vitrous 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 vitrous 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 Uiversity of Mdical Siences
Street address
Central Department No2, Tabriz University of Medical Sciences, Golgasht st
City
Tabriz
Postal code
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 Intravitral Avastin and Tissue Plasminogen Activator will be injected
Category
Treatment - Surgery

2

Description
For the 25 patients Intravitral 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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Nikookari Eye Hospital- Abbasi St.
City
Tabriz

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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Tabriz
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

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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