Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative study of the effect of intravitreal injection of bevacizumab versus simultaneous intravitreal injection of bevacizumab and triamcinolone acetonide in patients with retinal venous occlusion

Protocol summary

Study aim

Comparative study of the effect of intravitreal injection of bevacizumab versus simultaneous intravitreal injection of bevacizumab and triamcinolone acetonide

Design

This is a randomized clinical trial study in a parallel design. This study is randomized, phase 2-3 study will be performed on 58 eligible patients. A simple randomization method is used for randomization and participants are assigned to two intervention groups.

Settings and conduct

This study, which will be conducted in Imam Khomeini hospital of Kermanshah, is a double-blinded one. In this study, patients are aware of the study participation, but the person who injects drugs and the participants are kept blind to the type of medication and their dose. All intravitreal injections in the operating room will be performed after preparing the eye with betadine and anesthesia using 0.5% tetracaine drops and placement of the eyelid speculum and using a G 27 needle from the supratemporal part with a distance of 4 mm from the limbus.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who have had retinal vein occlusion in the last 12 weeks Exclusion criteria: History of any previous treatment, including macular laser or intravitreal injection; Having ocular hypertension; Vision better than 20/40 or central macular thickness less than 250 microns; Any type of neovascularization or with retinal arterial occlusion or symptoms in favor of treatment such as cilioretinal and retinal shunts

Intervention groups

In the first intervention group, intravitreal injection of 1.25 mg/0.05 mL bevacizumab (Darou Pakhsh Company) will be performed monthly for six months. In the second intervention group, intravitreal injection of 0.05 cc 1.25 mg bevacizumab (Darou Pakhsh Company) and 2 mg/0.05 ml triamcinolone (Darou Pakhsh Company) will be performed two months apart for six months.

Main outcome variables

Vision

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N185**
Registration date: **2022-05-25, 1401/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-25, 1401/03/04**
Update count: **0**

Registration date

2022-05-25, 1401/03/04

Registrant information

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Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-14, 1401/01/25

Expected recruitment end date

2022-10-17, 1401/07/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of intravitreal injection of bevacizumab versus simultaneous intravitreal injection of bevacizumab and triamcinolone acetonide in patients with retinal venous occlusion

Public title
Comparative study of the effect of intravitreal injection of bevacizumab versus simultaneous intravitreal injection of bevacizumab and triamcinolone acetonide
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who have had retinal vein occlusion in the last 12 weeks based on their history
Exclusion criteria:
History of any previous treatment, including macular laser or intravitreal injection Having ocular hypertension Vision better than 20/40 or central macular thickness less than 250 microns Media opacity Any type of neovascularization or with retinal arterial occlusion or symptoms in favor of treatment such as cilioretinal and retinal shunts Any retinal disease
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Care provider

Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method. Fifty-four cards will be selected, and numbers from 1-54 will be inserted into the cards. The cards will be placed in an envelope. Two project staff took one card from the envelope each time and randomly will given the picked cards to the participants. Even numbers will be assigned to the intervention group and odd numbers to the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will be designed as a single-blind. Although patients will not be aware of the type of injected drug, because IVT injection causes Floaters, this study will be considered a single-blind study and, the project staff who is responsible for injecting the medications will be kept blind to the treatment groups. Medications can only be identified by the serial number on the container. The serials are with the main researcher and will remain confidential until the end of the study. The syringes are also similar, and for the group that will receive the two types of drugs, the drugs are combined in one syringe.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
City
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Province
Kermanshah
Postal code
6715847141
Approval date
2022-02-13, 1400/11/24
Ethics committee reference number
IR.KUMS.MED.REC.1400.131

Health conditions studied

1

Description of health condition studied
Retinal vascular occlusions
ICD-10 code
H34
ICD-10 code description
Retinal vascular occlusions

Primary outcomes

1

Description
Vision
Timepoint
First, one and six months after the end of the study
Method of measurement
using Snellen eye chart

Secondary outcomes

empty

Intervention groups

1

Description
In the first intervention group, an intravitreal injection of 1.25 mg/0.05 mL bevacizumab (Darou Pakhsh Company) will be performed monthly for six months.
Category
Treatment - Drugs

2

Description
In the second intervention group, intravitreal injection of 0.05 cc 1.25 mg bevacizumab (Darou Pakhsh Company) and 2 mg/0.05 ml triamcinolone (Darou Pakhsh Company) will be performed two months apart for six months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
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Position
Resident of Ophthalmology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available