

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

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

Kermanshah

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

Masoumeh Kariminia

Street address

Imam Khomeini Hospital, Naghliyah Street

City

Kermanshah

Province

Kermanshah

Postal code

6718443161

Phone

+98 83 3727 9104

Email

masume.kariminia1368@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

rkhodarahmi@kums.ac.ir

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

Kermanshah University of Medical Sciences

Full name of responsible person

Masoumeh Kariminia

Position

Resident of Ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

Street address

Imam Khomeini Hospital, Naghliyah Street

City

Kermanshah

Province

Kermanshah

Postal code

6718443161

Phone

+98 83 3727 9104

Email

masume.kariminia1368@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Pejvak Azadi

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Ophthalmology

Street address

Imam Khomeini Hospital, Naghliyeh Street

City

Kermanshah

Province

Kermanshah

Postal code

6718443161

Phone

+98 83 3727 8759

Email

Azadipe@yahoo.com

Ophthalmology

Street address

Imam Khomeini Hospital, Naghliyeh Street

City

Kermanshah

Province

Kermanshah

Postal code

6718443161

Phone

+98 83 3727 9104

Email

masume.kariminia1368@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Masoumeh Kariminia

Position

Resident of Ophthalmology

Latest degree

Medical doctor

Other areas of specialty/work**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