Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the effectiveness of ZIV-aflibercept (Zal-trap) in patients with retinal vascular disorders resistant to Avastin

Protocol summary

Summary

Objectives: The objective of the study is to evaluate the effectiveness of Zal-trap 0.125 mg and to identify its side effects in patients resistant to Avastin. Study Design: In this quasi-experimental interventional study, the total sample volume is calculated to be 17 patients. The control group is the preoperative status of the patients and no randomization is performed. Method: In a sterile manner, 0.05 ml zal-trap is injected into the Vitreous humour of the eye with a lower visual acuity (visual acuity less than 20/100) in patients with retinal vascular disorders (AMD, DME, and RVO) who require anti-VEGF treatment and have not responded to Avastin, after obtaining informed consent. The visual acuity of the patients will be monitored in the beginning of the study and 1 week and 1 month after the procedure. Participants: The inclusion criteria are eyes with AMD or active neovascular DME, best corrected visual acuity of 20/100 (06/30) or less, capability of comprehending the advantages and risks of the study, ability to sign the informed consent form, and lack of response to Avastin treatment. The exclusion criteria of the study are the signs of ocular infection, and a positive history of MI or CVA. Interventions: After applying local anesthesia and povidone-iodine, a sterile eyelid retractor will be used. In “one” eye of the patient, 0.05 ml (1.25 mg) Zal-trap that is already prepared from a 4ml vial is injected using a 30-gauge 1cc syringe. Main outcome variables including primary and secondary outcomes are visual acuity of the patients and the height of retinal pigment epithelial detachment, respectively.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015081723651N1**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-12, 1394/09/21

Registrant information

Name

Kamran Jalali

Name of organization / entity

Noor Hospital Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-08-27, 1394/06/05

Expected recruitment end date

2015-09-27, 1394/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of ZIV-aflibercept (Zal-trap) in patients with retinal vascular disorders resistant to Avastin

Public title

The effect of zaltrap in the treatment of retinal retinal vascular disorders resistant to Avastin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :Eyes with active neovascularage-related macular degeneration (AMD) or diabetic macular edema (DME), best-corrected visual acuity of 20/100 (6/30) or less, the ability to comprehend the risks and benefits of the study, and the ability to sign the consent form; Exclusion criteria : Signs of ocular infection and a history of myocardial infarction or cerebrovascular accident.

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences (TUMS)

Street address

Keshavarz Blvd., Qods Street; Tehran, Iran

City

Tehran

Postal code

1968653111

Approval date

2015-08-10, 1394/05/19

Ethics committee reference number

IR.TUMS.REC.1394.555

Health conditions studied

1

Description of health condition studied

Retinal vascular disorders

ICD-10 code

H30-H36

ICD-10 code description

Disorders of choroid and retina

Primary outcomes

1

Description

Best corrected visual acuities

Timepoint

In the beginning of the study, and 1 day and 1 week after Zal-trap injection

Method of measurement

By the same examiner, using Snellen charts

Secondary outcomes

1

Description

The height of retinal pigment epithelium detachment

Timepoint

In the beginning of the study and 1 day and 1 week after Zal-trap injection

Method of measurement

On the horizontal scan and vertical scan passing through the foveola through averaging the horizontal and vertical measures

Intervention groups

1

Description

one intravitreal injection 0.05 ml of ziv-ablicerpt in one eye of each patient with retinal disease(AMD, CRVO) and monitor vision and OCT 1 day and 1 week after injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Noor Eye Hospital

Full name of responsible person

Dr.Kamran Jalali

Street address

96, Esfandiar Blvd, Valiasr St.

City

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
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Street address
96, Esfandiar Blvd, Valiasr 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
Investigator
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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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