Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the changes in the OCT angiography after the Intra Vitreal Injection of Bevacizumab in diabetic Patients with Clinically Significant Macular Edema.

Protocol summary

Study aim
To determine changing in the OCT angiography after the Intravitreal injection of Bevacizumab in diabetic patients with clinically significant macular edema

Design
The trial of one group without control group, without blinding , with a sample size of 35 patients with diabetic macular edema

Settings and conduct
In this study, complete ophthalmology examination and OCTA are provided for 35 eyes of patients with clinically significant macular edema, Before and 1 month after intra vitreal injection of Bevacizumab (˝or stivant) . OCTA geometrical findings of FAZ area and thicknes are analyzed .

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with Diabetic macular edema. Exclusion criteria: Myopia more than 6 diopters; history of vitrectomy;macular hole ,CNV, Hydroxycloroquine consumption.

Intervention groups
Intervention group: Patients with diabetic macular edema. These patients will receive 1.25 mg of Bevacizumab (or Stivant), intravitreally by other specialist.

Main outcome variables
Change in macular thickness; change in FAZ area

General information

Reason for update
completion and correction of exclusion criteria and correction of some sentences that needs correction

Acronym

IRCT registration information
IRCT registration number: **IRCT20190518043622N1**
Registration date: **2020-09-04, 1399/06/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-15, 1399/08/25**
Update count: **1**

Registration date
2020-09-04, 1399/06/14

Registrant information
Name
Arash ghazanfari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3633 3615
Email address
arash.ghazanfari@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-04, 1397/03/14

Expected recruitment end date
2021-07-10, 1400/04/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the changes in the OCT angiography after the Intra Vitreal Injection of Bevacizumab in diabetic Patients with Clinically Significant Macular Edema.

Public title
Evaluation of Bevacizumab effect on diabetic macular

edema in diabetic patients .

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic macular edema age between 30-75 years old Central macular thickness more than 300 microne based on OCT measurement

Exclusion criteria:

Myopia more than 6 diopters other macular diseases like macular hole and CNV Some drugs :Hydroxycloroquine consumption Previous history of chemotherapy and radiotherapy History of vitrectomy

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

In this study, we assessed features of OCT Angiography images to find vascular and morphological changes before and after the injection of Bevacizumab.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Floor 7, Central building of Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2018-05-21, 1397/02/31

Ethics committee reference number

IR.SUMS.MED.REC.1397.079

Health conditions studied

1

Description of health condition studied

Diabetic macular edema

ICD-10 code

H36.0

ICD-10 code description

Diabetic retinopathy

Primary outcomes

1

Description

Change in macular thickness

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Evaluation of macular thickness with OCT angiography

2

Description

Change in geometrical feature of FAZ area

Timepoint

Before intervention and 1 month after intervention

Method of measurement

Evaluation of geometrical features of macula with OCT angiography and analyzing it with MATLAB

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intravitreal injection of 1.25 mg of Bevacizumab(or stivant) will be performed by other expert in operation room under sterile condition (for patients with diabetic macular edema). The patients will be followed before and one month after operation. In this study we did not intervene and we analyzed the OCTA images before and after what other experts injected to evaluate macular changes.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Postchi Ophthalmology Center

Full name of responsible person

Mohammad Hosein Norooz zade
Street address
Ophthalmology Clinic of Poostchi , Zand Boulevard, Shiraz
City
shiraz
Province
Fars
Postal code
7134997446
Phone
+98 71 3230 2830
Email
poostchi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Floor 7, Central bulding of Shiraz University of Medical Sciences, Zand Blvd, Shiraz
City
Shiraz
Province
Fars
Postal code
71347-14336
Phone
+98 71 3235 7282
Email
Vcrdep@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Arash Ghazanfari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
Street address
Unit 1, Baran building (No 169), Takestan avenue, Rajaee boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
7185955766
Phone
+98 71 3633 3615
Email
Arash.ghazanfari@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Arash ghazanfari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology
Street address
Unit 1, Baran building (No 169), Takestan avenue, Rajaee boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
7185955766
Phone
0987136333615
Email
arash.ghazanfari@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Arash Ghazanfari
Position
Resident of ophtalmology
Latest degree
Medical doctor
Other areas of specialty/work
Ophthalmology

Street address
Unit 1, Baran building (No 169), Takestan avenue, Rajaee boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
7185955766
Phone
+98 71 3633 3615
Fax
Email
arash.ghazanfari@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available