

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of intravitreal injection of Bevacizumab and subtenon injection of Triamcinolone and topical diclofenac eye drop in preventing the incidence of diabetic macular edema after phaco with intraocular lens implementing

Protocol summary

Summary

This study is a prospective and randomized single blind clinical trial. The aim of this study is effect of intravitreal injection of Bevacizumab and subtenon injection of Triamcinolone and topical diclofenac eye drop in preventing the incidence of diabetic macular edema after phaco with intraocular lens implementing. Total of sample size is 45 patient with ages: 18-70 years old. The patients with diabetic macular edema, glaucoma, any history of eye surgery six months before the study will be excluded. Inclusion criteria is diabetic patients with cataract and without diabetic macular edema. Assessor of study do not know about type of drug and grouping patients. This study is 3 trial phase. All patients are undergoing phaco surgery with intraocular lens. The patients are randomly divided into three groups by blocked randomization. Each group is consisted of fifteen patients. The first group receives 1.25 milligram of intravitreal Bevacizumab injection at the end of the surgery. The second group receives 4 milligram of subtenon Triamcinolone injection at the end of the surgery. The third group as a control group receives topical diclofenac eye drop every 8 hours until 4 weeks after surgery. Patients basic information such as age and sex, stature, BMI will be recorded in both groups before intervention. Macular thickness and visual acuity and intraocular pressure will be recorded one and three months after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050833875N1**

Registration date: **2017-06-30, 1396/04/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-30, 1396/04/09

Registrant information

Name

Aram Mohamad Jafari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravitreal injection of Bevacizumab and subtenon injection of Triamcinolone and topical diclofenac eye drop in preventing the incidence of diabetic macular edema after phaco with intraocular lens

implementing	
Public title	Effect of diclofenac eye drop and Bevacizumab and Triamcinolone in preventing part of the retina edema
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion Criteria: Diabetic patients with cataract and without diabetic macular edema; Nonproliferation diabetic retinopathy. Exclusion Criteria: Glaucoma; Eye trauma; Laser therapy 12 months prior to cataract surgery; Any history of eye surgery 6 months ago.
Age	From 18 years old to 70 years old
Gender	Both
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 45
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	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences
Street address	Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz
City	Ahvaz
Postal code	
Approval date	2017-05-20, 1396/02/30
Ethics committee reference number	IR.AJUMS.REC.1396.139
Health conditions studied	

<u>1</u>	
Description of health condition studied	Diabetic retinopathy
ICD-10 code	H36.0
ICD-10 code description	Diabetic retinopathy
Primary outcomes	
<u>1</u>	
Description	Macular thickness
Timepoint	Before the surgery and one month and three months after surgery
Method of measurement	spectral domain optical coherence tomography (SD-OCT)
<u>2</u>	
Description	Visual acuity
Timepoint	Before the surgery and one month and three months after surgery
Method of measurement	Snellen chart
<u>3</u>	
Description	Intraocular pressure
Timepoint	Before the surgery and one month and three months after surgery
Method of measurement	Goldman tonometer
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	Group I (intervention group): Prescription 1.25 milligram of intravitreal Bevacizumab injection at the end of the surgery.
Category	Prevention
<u>2</u>	
Description	Group II (intervention group): Prescription 4 milligram of subtenon Triamcinolone injection at the end of the surgery.
Category	

Prevention

3

Description

Group III (control group): Prescription topical diclofenac eye drop every 8 hours until 4 weeks after surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Mostafa Fegghi

Street address

Khomeini Hospital, ShahidAhwazian St., Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

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 Of Ahvaz Jundishapur University of Medical Sciences

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Aram Mohamad Jafari

Position

Resident of ophthalmology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Eye surgery and professor cornea

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Person responsible for updating data

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Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sanaz Nazari

Position

Nurse of Anesthesia

Other areas of specialty/work

Street address

City

Postal code

Phone

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Fax
Email
Web page address

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