Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Name of organization / entity
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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

1

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

1

Description of health condition studied
Diabetic retinopathy
ICD-10 code
H36.0
ICD-10 code description
Diabetic retinopathy

Primary outcomes

1

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)

2

Description
Visual acuity
Timepoint
Before the surgery and one month and three months after surgery
Method of measurement
Snellen chart

3

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

1

Description
Group I (intervention group): Prescription 1.25 milligram of intravitreal Bevacizumab injection at the end of the surgery.
Category
Prevention

2

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 Feghhi
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Khomeini Hospital, ShahidAhwazian St., Ahwaz
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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
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Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz
City
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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
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
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Person responsible for updating data

Contact
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Phone
00

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