

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Iran (Islamic Republic of)

###### Phone

+98 61 3222 2922

###### Email address

mohamadjafari.a@ajums.ac.ir

##### 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 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

##### Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

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+98 61 3222 2922

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arammohamadjafary@yahoo.com

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Full name of responsible person

Mahmood Panahibazaz

##### Position

Eye surgery and professor cornea

##### Other areas of specialty/work

##### Street address

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##### Web page address

## Person responsible for updating data

#### Contact

##### 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*