

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The effect of intravitreal adalimumab injection on pseudophakic macular edema

#### Protocol summary

##### Summary

Today pseudophakic macular edema is a frequent cataract surgery complication. Inflammation is the major etiologic factor in the development of cystoid macular edema (CME) following cataract surgery. Adalimumab (Humira) is a TNF inhibitor which has been approved in the United States in addition to infliximab and Etanercept. The present study will be carried out, since no study has been done to determine the effect of Adalimumab in pseudophakic macular edema. Clinical examination include: best-corrected visual acuity (BCVA), applanation tonometry, fundus examination and OCT. A vial of adalimumab (Humira) containing 40 mg/0.8 ml will be mixed with 0.8 ml of balanced salt solution (BSS), and 0.08 ml (2 mg of adalimumab) of this solution will be prepared for each patient. After preparing the eye in a standard fashion using 5 % povidone/iodine, an eyelid speculum will be used to stabilize the eyelids, and the injection of 1 mg (0.05 ml) will be performed 3.5 - 4 mm posterior to the limbus, through the inferotemporal pars plana with a 30-gauge needle under topical anesthesia or subconjunctival lidocaine. After the injection patients will be instructed to administer topical antibiotics for 3 days. All patients will be given detailed post-injection instructions and to call if any pain or significant changes in vision. The patients were examined with slit-lamp biomicroscope and OCT .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016100430130N1**  
Registration date: **2016-12-03, 1395/09/13**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-03, 1395/09/13

##### Registrant information

###### Name

Mohsen Farvardin jahromi

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3230 2830

###### Email address

farvardm@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2016-10-16, 1395/07/25

##### Expected recruitment end date

2016-11-05, 1395/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intravitreal adalimumab injection on pseudophakic macular edema

##### Public title

The effect of intravitreal adalimumab injection on pseudophakic macular edema

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients with pseudophakic macular edema and PCIOL in bag who have received prior treatment (topical NSAIDs or topical corticosteroids).  
Exclusion criteria: patients with macular edema due to causes other than pseudophakia (diabetes, uveitis, retinitis pigmentosa); complicated surgery (vitreous loss); PCIOL in sulcus and ACIOL.

#### Age

From **40 years** old to **85 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **5**

#### 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

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences central building,  
Zand BLVD, Shiraz, Iran

##### City

Shiraz

##### Postal code

#### Approval date

2013-10-10, 1392/07/18

#### Ethics committee reference number

92-01-01-6327

## Health conditions studied

### 1

#### Description of health condition studied

Pseudophakic macular edema

#### ICD-10 code

H35.8

#### ICD-10 code description

Other specified retinal disorders

## Primary outcomes

### 1

#### Description

Visual acuity

#### Timepoint

Before injection, 1 week and 1 month after injection

#### Method of measurement

Snellen chart

## Secondary outcomes

### 1

#### Description

Central macular thickness

#### Timepoint

Before injection, 1 week and 1 month after injection

#### Method of measurement

OCT

## Intervention groups

### 1

#### Description

intravitreal adalimumab injection

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Khalili hospital

##### Full name of responsible person

Doctor Mohsen Farvardin

##### Street address

Iran

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shiraz University of  
Medical Sciences

##### Full name of responsible person

Dr. Sayed Basir Hashemi

##### Street address

Shiraz University of Medical Sciences central building,  
Zand BLVD, Shiraz, Iran

##### City

Shiraz

#### 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, Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Doctor Mohsen Farvardin

**Position**

posterior segment fellowship

**Other areas of specialty/work****Street address**

Shiraz University of Medical Sciences central building, Zand BLVD, Shiraz,

**City**

Shiraz

**Postal code****Phone**

+98 71 3230 5410

**Fax****Email**

farvardm@sums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

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**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*