Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 pseodophakic 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 % povodine/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 (vitrous 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 Univercity 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

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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