

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Outcomes of primary iris claw intraocular lens implantation for correction aphakia in comparison with scleral fixation intraocular lens implantation during pars plana deep vitrectomy

#### Protocol summary

##### Summary

In this prospective non-randomized clinical trial, we evaluated outcomes of primary iris claw intraocular lens implantation for correction aphakia in comparison with scleral fixation intraocular lens implantation during pars plana deep vitrectomy, in Imam Khomeini hospital of Ahwaz between September 2009 and September 2010. Intervention was performed only in one group and 12 patients who had inclusion criteria (dislocation of total crystalline lens v/s fragment of nucleus v/s IOL in vitreous after complicated cataract surgery or due to trauma and absence of capsular support) were enrolled in this study and operated simultaneously pars plana vitrectomy and IOL implantation. Patients of control group (13 patients) were selected retrospectively based on previous data. Outcomes included; uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), central corneal thickness (CCT), spherical equivalent (SE), and astigmatism were measured (preoperative and post operative) and compared between the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103116032N1**

Registration date: **2011-06-01, 1390/03/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-06-01, 1390/03/11

##### Registrant information

##### Name

Abbas Afkari

##### Name of organization / entity

Ahwaz Jondishapour University Of Medicine Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1444 1132

##### Email address

afkari.a@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahwaz Jondishapour University Of Medicine Science

##### Expected recruitment start date

2009-09-23, 1388/07/01

##### Expected recruitment end date

2010-09-16, 1389/06/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Outcomes of primary iris claw intraocular lens implantation for correction aphakia in comparison with scleral fixation intraocular lens implantation during pars plana deep vitrectomy

##### Public title

The evaluation of aphakic iris claw intraocular lens implantation results

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Dislocation of total crystalline lens v/s fragment of nucleus v/s IOL in vitreous after complicated cataract surgery or due to trauma, Absence of capsular

support for IOL implantation in capsular bag or ciliary sulcus Exclusion criteria: Uncontrolled glaucoma, recurrent uveitis history, severe iris damage, proliferative diabetic retinopathy, macular scar

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 25

#### 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

Ahwaz Jondishapour University Of Medicine Science

###### Street address

Golestan street, Aahvaz

###### City

Ahwaz

###### Postal code

6135715794

##### Approval date

2010-07-15, 1389/04/24

##### Ethics committee reference number

2192

### Health conditions studied

#### 1

##### Description of health condition studied

Aphakia

##### ICD-10 code

##### ICD-10 code description

### Primary outcomes

#### 1

##### Description

uncorrected visual acuity (UCVA)

##### Timepoint

one day preoperatively and the first day, third day, at the end of the first

##### Method of measurement

visual acuity without correction based on snellen chart at 6 meter

#### 2

##### Description

best corrected visual acuity (BCVA)

##### Timepoint

one day preoperatively and the first day, third day, at the end of the first

##### Method of measurement

visual acuity based on snellen chart at 6 meter,after correction.(based on subjective refraction

#### 3

##### Description

central corneal thickness (CCT)

##### Timepoint

one day preoperatively and the first day, third day, at the end of the first

##### Method of measurement

central corneal thickness (micron) based on Pachymetry

#### 4

##### Description

spherical equivalent (SE)

##### Timepoint

one day preoperatively and the first day, third day, at the end of the first

##### Method of measurement

spherical power (diopter) based on objective refraction.:  
S.E =Sphere+Cylinder/2

#### 5

##### Description

astigmatism

##### Timepoint

one day preoperatively and the first day, third day, at the end of the first

##### Method of measurement

cylinder power based on objective refraction

### Secondary outcomes

#### 1

##### Description

cystoid macular edema (complication)

##### Timepoint

one day preoperatively and the first day, third day, at the end of the first

##### Method of measurement

Edema in macular zone based on fundus examination.(confirmed by OCT)

## 2

### **Description**

Intra ocular pressure(IOP) increase (complication)

### **Timepoint**

one day preoperatively and the first day, third day, at the end of the first

### **Method of measurement**

IOP> 22 mmHg (Based on Goldmann Tonometer)

## 3

### **Description**

Retinal Detachment (complication)

### **Timepoint**

one day preoperatively and the first day, third day, at the end of the first

### **Method of measurement**

Based on fundus examination

## 4

### **Description**

lens haptic displacement (complication)

### **Timepoint**

one day preoperatively and the first day, third day, at the end of the first

### **Method of measurement**

Based on Slit Lamp examination

## **Intervention groups**

### 1

#### **Description**

The ARTISAN aphakia IOL is a polymethyl methacrylate IOL with an 8.5-mm length, and a 5.5-mm optical zone. In one group patients, initially a standard 3-port Pars Plana vitrectomy were performed. Crystalline lens or fragment of nucleus that dropped into vitreous extracted by phacofragmentation. Dislocated IOL in vitreous extracted from limbal incision. Then acetylcholine 1% was injected to constrict the pupil and from limbal incision an Artisan IOL was inserted in the anterior chamber. The iris was hooked between the claw-like footplates to achieve perfect IOL centration over the pupil. Finally, the incision was closed with 10-0 nylon sutures. Control group patients were selected retrospectively, from patients that undergo pars plana vitrectomy and sclera fixation Posterior Chamber IOL implantation in past.

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

#### **Name of recruitment center**

Imam Khomeini Hospital

#### **Full name of responsible person**

Abbas Afkari - ophthalmology resident

#### **Street address**

Azadegan.S

#### **City**

Ahwaz

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahwaz Jondishapour University Of Medicine Science

##### **Full name of responsible person**

Mostafa Fegghi

##### **Street address**

Golestan.S

##### **City**

Ahwaz

#### **Grant name**

#### **Grant code / Reference number**

10506

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Ahwaz Jondishapour University Of Medicine Science

#### **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**

Imam Khomeini Hospital

##### **Full name of responsible person**

Abbas Afkari

##### **Position**

ophthalmology resident

##### **Other areas of specialty/work**

##### **Street address**

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## **Person responsible for scientific inquiries**

### **Contact**

**Name of organization / entity**

Ahwaz Jondishapour University Of Medicine Science

**Full name of responsible person**

Feraidoon Farrahi

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## **Person responsible for updating data**

### **Contact**

## **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*