Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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, initialy 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 Feghhi
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
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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