

Cataract surgery with combined Primary Posterior Continuous Curvilinear Capsulorhexis (PPCCC) and Posterior Buttonholing (POBH) in comparison to conventional in the bag Intraocular Lens (IOL) implantation

Submission date 17/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/12/2020	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Cataract surgery with combined Primary Posterior Continuous Curvilinear Capsulorhexis (PPCCC) and Posterior Buttonholing (POBH) in comparison to conventional in the bag Intraocular Lens (IOL) implantation

Study objectives

A Primary Posterior Continuous Curvilinear Capsulorhexis (PPCCC) is the method of removing the central part or the posterior capsule during cataract surgery to prevent the formation of Posterior Capsule Opacification (PCO). One way to prevent lens epithelial cell growing on an intact vitreous face is using a buttonhole technique (Posterior Buttonholing [POBH]) to place the optic of the Intraocular Lens (IOL) posteriorly through the PCCC.

These recent improvements in surgical technique have reduced or delayed the incidence of PCO formation in adults. These new techniques could be a welcome addition to other attempts of preventing PCO. Therefore it is the aim of the present studies to compare the influence of PCCC, POBH and conventional in-the-bag implantation of IOL on PCO, visual acuity, and the axial IOL shift.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the Medical University of Vienna (Borschkegasse 8b/E 06, A-1090 Vienna, Austria) approved this study on the 13th March 2007 (ref: 067/2007).

Primary study design

Interventional

Study design

Prospective, randomised, single-masked clinical trial with within-patient comparison.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cataract surgery innovation

Interventions

Cataract surgery will be performed under topical anaesthesia through a 3.0 mm temporal self-sealing sclero-corneal tunnel incision. In all techniques, the Anterior Continuous Curvilinear Capsulorhexis (ACCC) with appropriate overlap of the IOL optic will be created using a needle. Thereafter hydrodissection, phacoemulsification and irrigation/aspiration of the lens will be performed.

In randomised order, cataract surgery with combined PPCCC and POBH will be performed in one eye; in the fellow eye cataract surgery will be performed conventionally with in-the-bag IOL implantation keeping the posterior lens capsule intact (standard procedure).

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

The following measurements will be performed preoperatively, at 1 day, 1 week, 1 month, and 8 - 12 months postoperatively:

1. Anterior and posterior capsule opacification
2. Intraocular lens position
3. Best corrected visual acuity
4. Contrast sensitivity
5. Optical Coherence Tomography (OCT) central retinal thickness
6. Postoperative vitreous detachment

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/12/2007

Eligibility

Key inclusion criteria

1. Patients with age-related cataract on both eyes awaiting bilateral same-day cataract surgery
2. Age range: 55 - 88 years, both male and female

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

50

Key exclusion criteria

1. Anamnesis or clinical signs of uveitis
2. Glaucoma
3. Proliferative diabetic retinopathy
4. Trauma
5. Small pupil
6. Previous ophthalmic operation

Date of first enrolment

20/08/2007

Date of final enrolment

01/12/2007

Locations

Countries of recruitment

Austria

Study participating centre

Department of Ophthalmology

Vienna

Austria

A -1090

Sponsor information

Organisation

The Medical University of Vienna (Austria)

ROR

<https://ror.org/05n3x4p02>

Funder(s)

Funder type

University/education

Funder Name

The Medical University of Vienna (Austria) - internally funded

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type

Details

Date created

Date added

Peer reviewed?

Patient-facing?

Results article	intraocular pressure results	01/11/2010	31/12/2020	Yes	No
Results article	macular morphology results	01/07/2008	31/12/2020	Yes	No