# 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	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
17/08/2007		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
26/10/2007	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
31/12/2020	Surgery			

# **Plain English summary of protocol**Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

## Protocol serial number

N/A

# 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).

#### Study design

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

# Primary study design

Interventional

## 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

A-1090

Study participating centre
Department of Ophthalmology
Vienna
Austria

# 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