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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

Registration date
26/10/2007

Overall study status
Completed

Last Edited
31/12/2020

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
20/08/2007

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

Age group
Adult

Sex
Both

Target number of participants
60 patients (120 eyes)

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)

Sponsor details
Waehringer Guertel 18-20
Vienna
Austria
A -1090

Sponsor type
University/education

Website
http://www.meduniwien.ac.at/index.php?id=372&language=2

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
The Medical University of Vienna (Austria) - internally funded

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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