

Clinical evaluation of two phacoemulsification tips: 23G phacoemulsification tip in comparison to 20G CMP phacoemulsification tip

Submission date 12/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2014	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Cataracts are cloudy patches that develop in the lens of the eye and can cause blurred or misty vision. Phacoemulsification cataract surgery is a procedure in which an ultrasonic device is used to break up and then remove a cloudy lens from the eye to improve vision. An artificial intraocular lens is then inserted into the eye. Modern micro-incision cataract surgery aims to reduce the size of the incision needed for the surgery by using smaller intraocular lenses and phacoemulsification tips. This may result in less operative trauma. The aim of this study is to compare a 23 gauge (G) phacoemulsification tip to a conventional 20G phacoemulsification tip for micro-incision cataract surgery.

Who can participate?

Patients aged 55-88 with age-related bilateral cataracts (i.e., in both eyes) and scheduled to undergo bilateral cataract surgery at our hospital.

What does the study involve?

A conventional 23G phacoemulsification tip will be used for the cataract surgery in one eye, while in the other eye cataract surgery will be performed with a 20G phacoemulsification tip. The follow-up care will be at our hospital. Visits will be 1 week and 6 months after surgery. The visits will include standard postoperative care and a measurement of the cornea of the eye.

What are the possible benefits and risks of participating?

Cataract operations are generally very successful, with a low risk of serious complications. We do not expect any additional risk due to participation in the study. There may be no direct benefits for the participants, but the smaller incisions used for the 23G tip may lead to a faster recovery.

Where is the study run from?

Medical University of Vienna (Austria).

When is the study starting and how long is it expected to run for?

The study ran from April 2008 to April 2011.

Who is funding the study?
Medical University of Vienna (Austria).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
690/2007

Study information

Scientific Title
Clinical evaluation of two phacoemulsification tips: 23G phacoemulsification tip in comparison to 20G CMP phacoemulsification tip - a randomised trial

Study objectives
To compare the intraoperative efficiency, safety and postoperative outcomes after cataract surgery with two different phacoemulsification tips - 23G phacoemulsification tip for co-axial higher-fluidics phacoemulsification compared to CMP 20G phacoemulsification tip for co-axial lower-fluidics phacoemulsification.

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), 13/03/2007, EK-Nr.: 690/2007

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

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 intraocular lens (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 a 23G phacoemulsification tip will be performed in one eye; in the fellow eye cataract surgery will be performed with the 20G phacoemulsification tip.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Phacoemulsification time (sec)
2. Maximum phacoemulsification power (%)

Key secondary outcome(s)

1. Overall surgery time (min)
2. Length of corneal incision (mm)
3. Stability of anterior chamber
4. Corneal stress (semiquantitatively)
5. Anterior chamber flare measurement (LFCM)
6. Corneal endothelial cell count
7. Pachymetry
8. Corneal topography and keratometry

Completion date

01/04/2011

Eligibility

Key inclusion criteria

1. Patients with age-related cataracts in 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

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

01/04/2008

Date of final enrolment

01/04/2011

Locations**Countries of recruitment**

Austria

Study participating centre

Department of Ophthalmology

Vienna

Austria

1090

Sponsor information**Organisation**

Medical University of Vienna (Austria)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Medical University of Vienna (Austria)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration