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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

Registration date
10/08/2012

Overall study status
Completed

Last Edited
12/06/2014

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Dr Rupert Menapace
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2008

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

Age group
Adult

Sex
Both

Target number of participants
50 patients (100 eyes)

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)

Sponsor details
Medical University of Vienna
Waehringer Guertel 18-20
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medical University of Vienna (Austria)

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