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Comparison of two cataract surgery techniques: conventional phacoemulsification vs femtosecond laser-assisted cataract surgery

Submission date
25/02/2017

Recruitment status
No longer recruiting

Registration date
13/03/2017

Overall study status
Completed

Last Edited
05/02/2019

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cataracts are a condition in which the natural lens inside the eye can become cloudy and hard, leading to visual problems. They can develop from normal aging, from an eye injury, or after taking certain types of medications. Cataract surgery involves removing the affected lens and replacing it with a clear artificial one (intraocular lens). Modern cataract surgery is usually performed using a technique called phacoemulsification, also called small-incision surgery. This is where ultrasound waves (high-frequency sound waves) are used to break up the affected lens in the eye and mixed with a salt water solution (saline) that is injected into the eye by the phacoemulsification machine (emulsification), so it can be sucked (aspirated) out through a tiny cut in the cornea (transparent layer forming the front of the eye). The replacement lens is then injected through the cut in the cornea into the correct position. Over the last 5-10 years, a technique called femtosecond laser assisted cataract surgery (FLACS) has been developed and introduced into the European Union. In this technique, femtosecond laser is used to perform some of the surgical steps, potentially increasing surgical precision and postoperative outcomes. The aim of this study is to compare the effectiveness of these two types of surgery.

Who can participate?
Patients over 50 years of age with with cataracts in both eyes.

What does the study involve?
Participants are randomly allocated to have a different surgical procedure performed on each eye. On one eye, participants have the usual phacoemulsification procedure performed. This involves using ultrasound waves to break up the affected lens in the eye and mixed with a salt water solution that is injected into the eye by the phacoemulsification machine so it can be sucked out through a tiny cut in the cornea (transparent layer forming the front of the eye) and then be replaced. On the second eye, the FLACS procedure is performed. This involves using a special laser to break up the affected lens so that it can be replaced. Participants in both groups undergo eye tests one day, one week and one, three and six months after surgery to find out which procedure is the most effective.

What are the possible benefits and risks of participating?
It is no currently known whether participants will benefit from taking part as the difference in the effectiveness of the techniques being used in this study is unknown. There are no notable risks involved with participating.

Where is the study run from?
Donostia Universitary Hospital (Spain)

When is study starting and how long is it expected to run for?
October 2013 to January 2015

Who is funding the study?
Mediker (Spain)

Who is the main contact?
Dr Javier Mendicute
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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
883PLP DSS 013-14

Study information

Scientific Title
Cataract surgery prospective comparative clinical trial: femtosecond laser assisted cataract surgery vs conventional phacoemulsification

Study objectives
The aim of this study is to determine whether the advantages related to laser-assisted cataract surgery have an effect on cataract patients in Donostia University Hospital.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gipuzcoa Healthcare Area Clinic Investigation Ethics Committee (Comité Ético de Investigación Clínica del Área Sanitaria de Gipuzkoa), 24/09/2013

Study design
Single-centre prospective intra-participant randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cataract

Interventions
Following provision of informed consent, participants eyes are randomised to receive conventional phacoemulsification or femtosecond laser-assisted cataract surgery on one of their eyes, and receive the technique not used on their other eye. Randomisation is undertaken using computer randomisation.

Group 1: Eyes that are randomised for conventional phacoemulsification are operated following standard phaco-chop techniques using the Infinity phacoemulsification system.

Group 2: Eyes that are randomised for femtosecond laser-assisted cataract surgery undergo femtosecond laser pretreatment with the Victus Femtosecond Laser Platform and phacoemulsification with the Infinity phacoemulsification system follows.

The same experienced surgeon performs all surgeries. Phacoemulsification parameters, viscoelastic device and monofocal intraocular lens are the same for all eyes. Preoperative sedation and midriasis protocol and postoperative topical treatment are the same in all cases.

Follow up involves visual acuity and quality determination, aswell as endothelial analysis, IOL position assessment and macular and optic nerve evaluation. Postoperative visits are programmed 1 day, 1 week, 1, 3 and 6 months after surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Uncorrected distance visual acuity is measured using the logMAR scale pre-operatively, 1 day, 1 week, 1, 3 and 6 months after surgery
2. Best distance corrected visual acuity is measured using the logMAR scale pre-operatively, 1 week, 1, 3 and 6 months after surgery.
3. Objective optical quality is measured using the OQAS -Optical Quality Analysis System pre-operatively, 1 day, 1 week, 1, 3 and 6 months after surgery
4. Refraction is measured using an autorefractometer pre-operatively, 1 day, 1 week, 1, 3 and 6 months after surgery

Secondary outcome measures
1. Phacoemulsification is assessed using the inifinity phacoemulsification machine at the end of surgery at the surgical visit.
2. Endothelial cell quantitative and morphologic analysis is measured using a SP-3000 specular microscope pre-operatively, 1 day, 1 week, 1, 3 and 6 months after surgery
3. IOL position is assessed by measuring the torizontal tilt using a TMS-5 Scheimpflug Topographer 1 day, 1 week, 1, 3 and 6 months after surgery and IOL decentration using Adobe Photoshop 1 week, 1, 3 and 6 months after surgery.
4. Macular thickness is measured using the Cirrus-HD OCT (macular cube 512x128) pre-operatively, 1 week, 1, 3 and 6 months after surgery
5. Optic nerve retinal nerve fiber layer (RNFL) and morphologic parameters are measured using the Cirrus-HD OCT (optic disc cube 200x200) pre-operatively, 1 week, 1, 3 and 6 months after surgery

Overall study start date
01/10/2013

Completion date
30/01/2015

Eligibility

Key inclusion criteria
1. Patients of over 50 years of age
2. Healthy eyes with cataract
3. IOL implantation in capsular bag with injector
4. Signed informed consent
5. Follow-up exam assistance assured

Participant type(s)
Patient

Age group

Senior

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Pseudophakia
2. Cornea guttata; corneal degeneration
3. Irregular astigmatism; keratoconus
4. Corneal scarring
5. Keratoplasty
6. Glaucoma
7. Intraocular inflammatory process and/or other preexistant events that could possibly permanently limit postoperative best corrected visual acuity
8. Amblyopia
9. Retinal detachment surgery
10. Any kind of macular degeneration or retinal alterations
11. Intraocular tumours
12. Capsular bag condition that contraindicates intraocular lens implantation
13. Intraoperative complications Complicaciones intraoperatorias
14. Pregnancy or lactation

Date of first enrolment
28/10/2013

Date of final enrolment
02/07/2014

Locations

Countries of recruitment
Spain

Study participating centre
Donostia University Hospital
Paseo del Dr. Beguiristain s/n
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Sponsor information

Organisation
Mediker

Sponsor details
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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Mediker

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Javier Mendicute (jmendicu@chdo.osakidetza.net)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/08/2018	05/02/2019	Yes	No