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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
25/02/2017		☐ Protocol			
Registration date 13/03/2017	Overall study status Completed	Statistical analysis plan			
		[X] Results			
Last Edited	Condition category	[] Individual participant data			
05/02/2019	Eve Diseases				

#### 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

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

risks involved with participating.

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
jmendicu@chdo.osakidetza.net

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Javier Mendicute

#### Contact details

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# Additional identifiers

Protocol serial number 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

# Study type(s)

Treatment

#### 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(s)

- 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 preoperatively, 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

#### Key secondary outcome(s))

- 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) preoperatively, 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

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Senior

#### Sex

All

#### 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 San Sebastian Spain 20014

# Sponsor information

# Organisation

Mediker

# Funder(s)

# Funder type

Research organisation

#### **Funder Name**

Mediker

# **Results and Publications**

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes