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Evaluation of a low-energy femtosecond laser in cataract surgery

Submission date	Recruitment status	[ ] Prospectively registered
03/07/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/08/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/09/2018	Eye Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cataracts are a condition where the lens of the eye becomes cloudy, which leads to a decrease in vision. Cataracts can be treated with laser surgery, where lasers are used to tell the surgeon the correct locations of the eye to perform the surgery and remove the cataract.
A type of laser called a femtosecond laser can be used to standardise and increase the safety and accuracy of laser surgery for cataracts. Bimanual microincision cataract surgery (B-MICS) is a technique that makes the surgery less invasive, more stable and more precise. Femtosecond lasers and B-MICS therefore appear to be well-suited to use in combination. As a result, we aim to look at the safety and efficacy of combining femtosecond lasers with B-MICS during cataract surgery performed by a well-trained surgeon.

Who can participate?
Patients aged over 50 with cataracts with nuclear sclerosis grade 2 and 3

What does the study involve?
Participants will receive cataract surgery using either the B-MICS technique only (control group) or femtosecond laser-assisted B-MICS, depending on whether their surgery is scheduled for the day the femtosecond laser is available or not. Patients will also undergo measurements including visual acuity, corneal astigmatism and corneal thickness before the surgery and 7 days, 1 month and 3 months later. Patients will receive a follow up after 18 months to check for complications and determine the success of the surgery.

What are the possible benefits and risks of participating?
The possible benefit to participants of taking part is a faster recovery, due to lower endothelial damage and corneal edema. The possible risks to participants are standard risks of cataract surgery, including complications during the operation (endothelial damage, capsule breakgae or a dropped nucleus) and after the operation (infections, macular edema, intraocular lens dislocation and an increase in intraocular pressure.

Where is the study run from?
Institute of Ophthalmology, University of Modena and Reggio Emilia, Italy

When is the study starting and how long is it expected to run for?
January 2015 to December 2019

Who is funding the study?
Fondazione Cassa di Risparmio di Modena (Italy)

Who is the main contact?
Prof Gian Maria Cavallini
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol 4010/CE - Serial number 202/15

Study information

Scientific Title
Evaluation of bimanual femtosecond laser-assisted cataract surgery with low energy LDV Z8

Acronym
Bimanual-FLACS

Study objectives
The femtosecond laser was introduced in ophthalmology more than 7 years ago to assist in precision cataract surgery. This new technique offers advantages in terms of reproducibility and precision in comparison to standard phacoemulsification by helping the surgeon for the creation of microincisions, capsulotomies and nucleus fragmentation. Bimanual microincision cataract surgery (B-MICS) is a minimally invasive variant of coaxial phacoemulsification which enables microincisions of 1.4 mm. This technique is characterized by increased stability of the anterior

chamber with the separation of the aspiration and the infusion probe; moreover, the small instruments give greater visibility of the surgical field. Because of the requirement of precision and small openings, the use a femtosecond laser is well suited to be associated with minimally invasive bimanual surgery. The purpose of this study is to evaluate the safety and efficacy of bimanual FLACS with a low-energy femtosecond laser. Data are compared with outcomes of the standard B-MICS technique. Intra- and post-operative complications, together with intra- and postoperative efficacy parameters are registered , such as visual acuity, astigmatism, corneal thickness and endothelial cell count. A long-term evaluation of the results will be investigated in particular

Ethics approval required
Old ethics approval format

Ethics approval(s)
Comitato Etico Area Vasta Emilia Nord, 23/10/2015, 202/15

Study design
Interventional non-randomised single-center prospective pilot trial

Primary study design
Interventional

Secondary study design
Non randomised study

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 participant information sheet

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

Interventions
After provision of written informed consent, consecutive patients with nuclear sclerosis grade 2 and 3 in the Lens Opacities Classification System III and in line for cataract surgery on the day in which the femtosecond laser was available are treated and enrolled into the current study (Group A). A control series of patients with similar baseline characteristics treated by the same experienced surgeon with standard B-MICS are selected for comparison (Group B).

Intervention Type
Procedure/Surgery

Primary outcome measure
The following outcomes measured at the baseline, 7 days, 1 month and 3 month follow-up:
1. Best corrected visual acuity (BCVA)

2. Corneal astigmatism
3. Central corneal thickness (CCT)
4. Endothelial cell count (ECC)
5. Central macular thickness (CMT)
6. Macular pigment optical density (MPOD)

Secondary outcome measures
The following outcomes measured at the 18 month long term follow-up:
1. Intraoperative parameters
2. Intra- and post-operative complications
3. Posterior capsule opacification
4. Capsulorhexis shape

Overall study start date
01/11/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Over 50 years of age
2. Nuclear sclerosis grade 2 and 3 in the Lens Opacities Classification System III (LOCS III)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Previous eye surgery
2. Complicated cataracts (e.g. hard cataracts, traumatic cataracts, pseudoesfoliation syndrome)
3. Insufficient mydriasis (less than 4 mm)
4. Concomitant eye pathologies (uveitis, glaucoma, corneal opacities, diabetic retinopathy)
5. Low endothelial cell count (less than 1500 cells/mm^2)

Date of first enrolment
01/01/2016

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Italy

Study participating centre
Institute of Ophthalmology, University of Modena and Reggio Emilia
Via Del Pozzo, 71
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41124

Sponsor information

Organisation
Institute of Ophthalmology, University of Modena

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/02d4c4y02

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

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. Tommaso Verdina, email: tommaso.verdina@gmail.com. Data will be available for all the duration of the study and will be shared either by mail or email. Consent was obtained from all participants.

IPD sharing plan summary
Available on request