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Evaluating femtosecond laser assisted cataract and lens surgery

Submission date
21/08/2012

Recruitment status
No longer recruiting

Registration date
30/08/2012

Overall study status
Completed

Last Edited
07/12/2017

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
In femtosecond laser-assisted surgery a laser is used to create tiny incisions in the eye through which the old cloudy lens or cataract is removed and the new lens is implanted. The system has recently been introduced into the European Union and clinical use is limited, so we are evaluating the use of this system.

Who can participate?
Adults (aged over 16) undergoing refractive lens or cataract surgery.

What does the study involve?
Data on the results of your surgery will be analysed. We will also carry out some additional tests before and after surgery to determine the health of your eyes.

What are the possible benefits and risks of participating?
The additional tests are all non-contact, non-invasive and involve no discomfort. It is likely to take a maximum of 1 hour of extra time to perform these. There is no additional charge for you to be part of the study. The measurements performed will be providing additional information about the health of your eyes. However, overall it is unlikely that you will benefit personally from helping with this research project, but the results of the research should be of benefit to the large number of patients in the future.

Where is the study run from?
Moorfields Eye Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2012 to August 2013

Who is funding the study?
Investigator initiated and funded (UK)

Who is the main contact?
Julian Stevens
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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
Protocol version 4.3

Study information

Scientific Title
Prospective observational study to evaluate femtosecond laser lens fragmentation, anterior capsulotomy cataract and lens extraction surgery

Study objectives
To describe the safety of femtosecond laser lens fragmentation and anterior capsulotomy assisted cataract and lens surgery

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City Road & Hampstead, 30/01/2012, ref: 12/LO/0042

Study design
Prospective observational study

Primary study design
Observational

Secondary study design
Non 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, refractive error

Interventions
This is an observational study of surgery outcomes.

Intervention Type
Procedure/Surgery

Primary outcome measure
To record any complications or adverse events

Secondary outcome measures
To describe the ability of the intraocular femtosecond laser to successfully perform an anterior capsulotomy and phakofragmentation during cataract/lens surgery.

Overall study start date
28/08/2012

Completion date
28/08/2013

Eligibility

Key inclusion criteria
Any subject planned to undergo femtosecond laser assisted lens surgery. These subjects will already meet these criteria:
1. Subjects must be adults (>16 years), undergoing refractive lens or cataract surgery
2. Subjects must provide informed consent, have signed the written informed consent form, and been given a copy
3. Subjects must have a calculated average corneal power after of ≤ 50.00 D in the eye to be implanted
4. Subjects must have a pharmacologically dilated pupil >6.0 mm, in the eye to be implanted

5. The central anterior chamber depth must be >2.0 mm (Pentacam)
6. Subjects must be willing and able to return for scheduled follow up examinations for 3 months after surgery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Subjects with subluxated crystalline lens
2. Subjects with endothelial dystrophy, guttata, in the eye to be implanted
3. Subjects with keratoconus (or keratoconus suspect) in the eye to be implanted or K>50 D
4. Subjects with distorted or unclear corneal mires on topography maps of the eye to be implanted
5. Subjects with a history of Herpes zoster or Herpes simplex keratitis.
6. The central anterior chamber depth <2.0 mm (Pentacam)
7. Tremor with head titubation
8. Subjects who are participating in any other ophthalmic drug or device clinical trial during the time of this clinical investigation

Date of first enrolment
28/08/2012

Date of final enrolment
28/08/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
81 Britannia Walk
London
United Kingdom
N1 7RH

Sponsor information

Organisation
Moorfields Eye Hospital (UK)

Sponsor details
c/o Sue Lydeard
Research & Development
162 City Road
London
England
United Kingdom
EC1V 2PD

Sponsor type
Hospital/treatment centre

Website
http://www.moorfields.nhs.uk/

ROR
https://ror.org/03tb37539

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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