# Evaluating femtosecond laser assisted cataract and lens surgery

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
21/08/2012		<pre>Protocol</pre>		
Registration date 30/08/2012	Overall study status Completed	Statistical analysis plan		
		Results		
Last Edited	Condition category	<ul><li>Individual participant data</li></ul>		
07/12/2017	Eye Diseases	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 info@julianstevens.co.uk

# Contact information

# Type(s)

Scientific

#### Contact name

Mr Julian Stevens

#### Contact details

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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  $\leq$  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