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FACT: laser-assisted versus standard ultrasound cataract surgery

Submission date
28/11/2014

Recruitment status
No longer recruiting

Registration date
06/01/2015

Overall study status
Completed

Last Edited
01/02/2021

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Cataracts are cloudy patches that develop in the lens of the eye and can cause blurred or misty vision. The only treatment that is proven to be effective for cataracts is surgery. Cataract surgery is the most commonly performed operation by the NHS with more than 310,000 operations performed in 2011-12. Cataracts are usually related to older age and as our population is ageing, we can expect the number of cataract operations to increase. While complication rates appear low, patients can be devastated when suffering a complication from surgery and due to the importance of vision for daily activities, can find even relatively minor complications distressing. This is a study comparing two different methods of cataract surgery. The current standard method is done by hand using ultrasound to break up the cataract. We want to compare this to a new technique using a computer-controlled laser system. The potential advantages of laser-assisted cataract surgery are that the steps completed by this method can be performed more precisely, more reliably and faster than they can be done by hand. This should translate to better visual outcomes and better patient safety as a result of fewer complications. The use of lasers in eye surgery is not new, and they have been used for surgery on the cornea (the structure at the front of the eye) for over a decade.

Who can participate?
Adults aged 18 or over with age-related cataracts in one or both eyes.

What does the study involve?
Participants will be randomly allocated so that half will have their cataract surgery done using the standard (ultrasound) method, and half will have the new laser-assisted method. The two types of surgery will be compared by looking at visual acuity, visual satisfaction through questionnaires, complications and health economic measures at 3 months following the first eye cataract surgery.

What are the possible benefits and risks of participating?
We cannot promise that taking part in the study will benefit you, but by taking part you will be helping us find out how laser-assisted cataract surgery compares to the current standard method. The results of the study will help to plan cataract services offered by the NHS. The study findings will provide high quality evidence to NHS service providers, patients and eye

specialists about these two methods of cataract surgery and so help guide any possible introduction of laser cataract surgery in the NHS. Studies to date on laser cataract surgery have reported no overall difference in serious complications when compared to standard ultrasound cataract surgery. Serious complications for both types of surgery are uncommon, but if they do occur they can permanently damage your eye and your vision. For cataract surgery done by either study method, there is an average:
1. One in a thousand risk of severe and permanent visual loss
2. One in a hundred risk of requiring additional surgery to rectify a problem
3. One in twenty risk of less serious complications, which may require further treatment at the time of surgery or following the operation
4. One in ten risk of laser treatment at some time in the future for opacity of the capsule behind the implant
There is virtually no risk to the other eye

Where is the study run from?
The study will be carried out at two sites, one is a Community Hospital in North London (St. Ann's Hospital), and the second is a District General Hospital in the West Midlands (New Cross Hospital, Wolverhampton).

When is the study starting and how long is it expected to run for?
The study will run from September 2014 to February 2018.

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Vicky McCudden (ctu.fact@ucl.ac.uk)
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Contact information

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Additional identifiers

Protocol serial number
14/0609; HTA 13/04/46

Study information

Scientific Title
The FACT trial: a randomised comparison of Femtosecond laser-assisted vs. manual phacoemulsification CataracT surgery for adults with visually significant cataract

Acronym
FACT

Study objectives
The trial is a pragmatic, randomised controlled non-inferiority trial to determine if the proposed advantages of laser-assisted cataract surgery translates to real benefits for both patients and the NHS.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/130446
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/130670/PRO-13-04-46.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - City Road & Hampstead, 06/02/2015, ref: 14/LO/1937

Study design
Pragmatic randomised controlled non-inferiority trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Symptomatic age-related cataract

Interventions
Arm A: manual phacoemulsification cataract surgery in the study eye
Arm B: laser-assisted phacoemulsification cataract surgery in the study eye

Intervention Type
Procedure/Surgery

Primary outcome(s)
Unaided distance visual acuity (UDVA, logMAR) at 3 months following surgery in the study eye measured using a standard ETDRS chart at a distance of 4 metres

Key secondary outcome(s))
1. Unaided distance visual acuity (UDVA) in the study eye at 12 months after surgery
2. Corrected distance visual acuity (logMAR) at 3 and 12 months after surgery in the study eye (ETDRS logMAR chart at 4 metres)
3. Ocular complications within 3 and 12 months of surgery in the study eye (and second eye). A complication will be defined as any event that causes unintentional injury to an ocular structure, or requires additional treatment, or has a negative effect on a patient's health or eyesight
4. Unaided and corrected visual distance acuity and complications in the second eye (for those with bilateral cataracts), and with both eyes open at 3 and 12 months after surgery
5. Percentage of patients within 0.5 and within 1 dioptre of intended refractive outcome
6. Patient-reported outcomes measures: vision health status using Rasch validated patient-reported outcome measures at 3 and 12 months: (Catquest-9SF)
7. Cost-utility analysis: within-trial cost-effectiveness analyses at 3 and 12 months and expected cost- effectiveness over patient lifetime. The analysis will conform to accepted economic evaluation methods and will use the EQ-5D-3L+vision bolt-on question (EQ-5DV)
8. Corneal endothelial cell count change (additional safety measure) at 3 and 12 months

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Adults aged 18 or over with symptomatic age-related cataract, one or both eyes
2. Patients must be sufficiently fluent in English to provide informed consent and completion of the patient-reported outcome measures
3. Patients must be willing to attend for follow up at 3 and 12 months after first eye cataract surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
785

Key exclusion criteria
1. Secondary causes of cataract
2. Previous cataract, corneal or glaucoma surgery
3. Patient unable to give consent or unable to attend follow-up assessment
4. Patient unable to be positioned for surgery
5. Patient scheduled to undergo combined surgery, e.g. cataract and trabeculectomy
6. Previously identified poor pupil dilation
7. Post-operative intended refractive target is not between (+0.50 and -0.50 dioptres) for the study eye

Date of first enrolment
01/05/2015

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St. Ann's Hospital
St. Ann's Road
London
United Kingdom
N15 3TH

Study participating centre
New Cross Hospital
Wednesfield Road
Heath Road
Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2020	11/05/2020	Yes	No
Results article	results	01/01/2021	01/02/2021	Yes	No

Protocol article	protocol	27/11/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes