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Phacoemulsification and changes in outflow facility

Submission date	Recruitment status	[X] Prospectively registered
27/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/04/2018	Eye Diseases	

Plain English summary of protocol

Background and study aims
Glaucoma is a treatable condition and is the second most common cause of blindness in the UK, and the world's leading cause of irreversible blindness affecting nearly 7 million. Based on information given by the International Glaucoma Association (IGA) website, glaucoma is the leading cause of preventable blindness in the UK and is estimated to affect over 500,000 people. Additionally, the information provided by the Royal National Institute for the Blind (RNIB) statistics, states that glaucoma is the second leading cause of blindness registered in the UK. Cataract is the most common cause of treatable blindness worldwide. Modern, small incision cataract extraction by phacoemulsification (small incision cataract surgery) with foldable intraocular lens implantation allows rapid visual rehabilitation and has a very high success rate. Phacoemulsification (small incision cataract surgery) is the most commonly performed cataract procedure in the developed world. Modern cataract surgery usually lowers eye pressure in eyes with glaucoma. The underlying mechanism of this is believed to be related to the increase in the flow of fluid out of the eyeball (fluid outflow), but little is known about these changes of fluid outflow in the eye after surgery (the drainage of the fluid is one of the determinants of eye pressure). The aim of this study therefore is to investigate the outflow facility changes in eyes with, and without, primary open angle glaucoma after phacoemulsification cataract surgery.

Who can participate?
Adults over 21 years old with reduced vision and glaucoma, and adults of the same age with reduced vision and no glaucoma.

What does the study involve?
All participants receive standard treatment, however the fluid outflow (drainage rate) from the front segment of the eye is also measured. This is done using tonometry, which is a standard procedure in which a local anaesthetic (numbing) drop is put in each eye and a small smooth instrument touches the surface of the eye for a few seconds to measure the eye pressure, and Shiotz Tonography, which involves lying down for 10 minutes while a technician makes a recording of the eye pressure in each eye for 4 minutes. An anesthetic drop is used so that participants do not feel the tonometer touching their eye while the tracing is made. Participants come back to the clinic after 3, 6 and 12 months so that the tests can be repeated.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating in this study. The procedures used in this study are not considered risky, however participants may experience a scratchy feeling of the eye and blurred (not clear and foggy) vision is commonly observed following the tonography test which usually lasts less than 30 minutes. As with any other test in which contact with the eye is required, such as tonometry, there is always a small chance of conjunctivitis (eye surface infection).

Where is the study run from?
St Thomas' Hosptial (UK)

When is the study starting and how long is it expected to run for?
October 2009 to October 2012

Who is funding the study?
EyeHope (UK)

Who is the main contact?
Mr Kin Sheng Lin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Phacoemulsification and changes in outflow facility in eyes with and without glaucoma

Study objectives
Changes of outflow facility after phacoemulsification in eyes with and without primary open angle glaucoma.

Further reading:
1. http://www.ncbi.nlm.nih.gov/pubmed/9261307
2. http://www.ncbi.nlm.nih.gov/pubmed/16488940
3. http://www.ncbi.nlm.nih.gov/pubmed/10966950
4. http://www.ncbi.nlm.nih.gov/pubmed/18452763
5. http://www.ncbi.nlm.nih.gov/pubmed/3579706
6. http://www.ncbi.nlm.nih.gov/pubmed/12714632
7. Moorfields manual of ophthalmology, 2008 Timothy Jackson, Mosby publications

Ethics approval required
Old ethics approval format

Ethics approval(s)
St. Thomas' Hospital Research Ethics Committee, 16/11/2009, ref: 09/H0802/103

Study design
Single-centre case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Glaucoma; outflow facility; phacoemulsification

Interventions
1. Visual acuity: using Snellen chart
2. Slit-lamp examination: including examination of the cornea for development of any signs of stromal oedema, gonioscopy using Zeiss or Goldmann gonioscopy lens in dimmed light (to

determine angle grade). Angle grading will be according to the Shaffers system. Prior to instillation of fluorescein or dilating pupil, aqueous flare and cells will be graded using a slit lamp beam with the height of 3 mm and width of 1 mm directed across the pupil.

Anterior chamber cells grading
Grade 0 = no cells
Grade 1 = 1 - 4 cells
Grade 2 = 5 - 19 cells
Grade 3 = greater than 20 cells
Grade 4 = presence of fibrin

Anterior chamber flare grading
Grade 0 = none
Grade 1 = visible flare
Grade 2 = iris details obscured

3. Goldmann applanation tonometry: A topical anaesthetic and fluorescein drop will be used. The study eyes IOP will be measured 3 times and the average will be recorded as the IOP.
4. Anterior chamber depth measurement. This non-contact measurement is done by using an ultrasound machine (IOL master, Carl Zeiss). This is a standard measurement needed for all patients prior to cataract surgery to measure their axial length and corneal power in order to calculate the power of replacement intraocular lens needed.
5. Outflow facility: The facility of outflow will be measured from the rate of decay of intraocular pressure in the supine position during application of a recording Schiötz tonometer over 4 minutes time. The "R" values of the curve at every 30 second time point will be manually entered into the McLaren tonography computer based program. The program fits a second degree polynomial by least squares to the nine data points and determines the best fit values for time 0 and time 4 minute by extrapolation. These initial and final values of the tonometer scale reading will be used to look up the value for the facility of outflow using 1955 scale approved by the Committee on Standardization of Tonometer.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Outflow facility is measured using electronic Shiotz tonography at 3, 6 and 12 months post cataract surgery

Secondary outcome measures
1. Anterior chamber depth is measured using IOL master at baseline
2. Intraocular pressure is measured using Goldmann applanation tonometer at baseline, 3, 6 and 12 months
3. Intra- or post-operative complications is measured using clinically intra-operatively and post operatively
4. Development of glaucoma is measured using clinically and Humphrey visual field at baseline and 12 months

Overall study start date

01/10/2009

Completion date
01/10/2012

Eligibility

Key inclusion criteria
1. Aged greater than 21 years
2. Lens opacity deemed enough to be causing reduced vision
3. Diagnosis of primary open angle glaucoma (POAG) (Group 1) or no glaucoma (Group 2). POAG defined as glaucomatous optic neuropathy together with an intraocular pressure (IOP) greater than 21 mmHg on at least one occasion, visual field defects (using the 24-2 test pattern on a Humphrey Field Analyser) and a gonioscopic angle width of 3 or 4 and normal in appearance.
4. Patient's willingness to participate in the study and ability to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20 patients in each groups

Key exclusion criteria
1. Previous intraocular surgery
2. Previous ocular trauma that can cause damage to the drainage angle (e.g. angle recession)
3. International normalised ratio (INR) greater than 3.0 on the day of surgery (for the patients on warfarin)
4. Anterior segment neovascularisation
5. Chronic use of systemic or topical steroid
6. Any other concurrent ocular disease e.g. uveitis, diabetic retinopathy, corneal diseae, etc.

Date of first enrolment
18/01/2010

Date of final enrolment
18/08/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St. Thomas' NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
EyeHope (UK)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.2	23/10/2009	04/08/2016	No	Yes
Results article	results	01/11/2018		Yes	No