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Comparison of postoperative parameters in cataract surgery with two different fluidic settings

Submission date 18/01/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/01/2016	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 20/01/2016	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cataracts are cloudy areas on the lens of the eye. They can appear for a number of reasons however they are most common in older people, developing over a long period of time (senile cataract). The lens sits near the front of the eye, and plays an important role in vision. When cataracts cause the lens to become clouded, it can prevent light from reaching the back of the eye (retina) to form an image that can be interpreted by the brain. When this happens, vision becomes blurred and distorted, and can eventually lead to blindness. Cataract surgery involves removing the affected lens and replacing it with a clear artificial one (intraocular lens). Modern cataract surgery is usually performed using a technique called phacoemulsification, also called small-incision surgery. This is where ultrasound waves (high-frequency sound waves) are used to break up the affected lens in the eye and mixed with a salt water solution (saline) that is injected into the eye by the phacoemulsification machine (emulsification), so it can be sucked (aspirated) out through a tiny cut in the cornea (transparent layer forming the front of the eye). The replacement lens is then injected through the cut in the cornea into the correct position. Many surgeons use different amounts of liquid for the emulsification. Some argue that using smaller amounts could help to prevent damage (trauma) to the eye than the standard amounts used, however further research is needed to find out whether this is the case. The aim of this study is to compare the amount of saline used with the overall effects on the eye following cataract surgery.

Who can participate?
Adults aged between 55 and 85 who have senile cataracts.

What does the study involve?
Participants are randomly allocated to one of two groups. All participants receive cataract surgery using the phacoemulsification technique to remove the affected lens before it is replaced by an artificial one. For those in group 1, the phacoemulsification machine is put on a low fluidic setting, which means a smaller amount of fluid is injected into the eye. For those in group 2, the phacoemulsification machine is put on a standard fluidic setting, which means that the normal amount of fluid is injected into the eye. For all participants, the length of surgery and

the amount of fluid used is measured for each procedure. At the start of the study and then again after 1 day, 3 weeks and 3 months, all participants have an eye exam in order to see if the procedure used has had an effect on their eye health (whether any eye damage has been caused).

What are the possible benefits and risks of participating?
Participants benefit from taking part as they receive thorough eye examinations which they would not normally be given. There are no risks of taking part in the study other than the general risks associated with cataract surgery.

Where is the study run from?
St. Erik Eye Hospital (Sweden)

When is the study starting and how long is it expected to run for?
October 2011 to April 2015

Who is funding the study?
1. Karolinska Institute (Sweden)
2. Stockholm County Council (Sweden)

Who is the main contact?
Dr Anthony Chang

Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparison of phacoemulsification cataract surgery with low versus standard fluidic sttings and the impact on postoperative parameters

Study objectives
Low compared fluidic settings in phacoemulsification cataract surgery is probably less traumatic compared to standard fluidic settings and can be evaluated by postoperative parameters indicating surgical trauma

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethical review board in Stockholm (Sweden), 26/02/2012, ref: Dnr 2011/2049

Study design
Single-centre prospective randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Postoperative complications in cataract surgery

Interventions
Participants will be randomised to receive either low- or standard fluidic settings. They will all be implanted with an AcrySof SN60WF intraocular lens (IOL).

Perioperatively the saline bag will be weighed before and after surgery to measure the amount of saline used. The saline for hydrodissection and wetting of the cornea is withdrawn before the first weight is measured. The Cumulative Dissipated Energy will be recorded as well as the surgery time. All operations will be videotaped with phacomachine lay over so that the energy used is shown at the end of surgery.

Patients will have a preoperative check, follow-up 1 day, 3 weeks and 3 months after surgery.

Intervention Type

Procedure/Surgery

Primary outcome measure
1. Duration of surgery is measured during surgery in minutes
2. Consumed balanced saline solution is determined by weighing the saline bag before and after surgery. The saline for hydrodissection and wetting of the cornea is withdrawn before the baseline measurement.
3. Cumulative dissipated energy is determined by recording the CDE-value from the LCD display of the Phacoemulsification machine
4. Central corneal thickness is measured with Anterior segment OCT at baseline, 1 day, 3 weeks and 3 months
5. Endothelial cell density is measured using confocal microscopy at baseline and 3 months
6. Anterior chamber flare is measured by laser flare meter at baseline, 1 day, and 3 weeks
7. Macular thickness is measured by OCT at baseline, 1 day, 3 weeks and 3 months

Secondary outcome measures
1. Intraocular pressure is measured using Goldmann applanation tonometry at baseline, 1 day, 3 weeks and 3 months
2. Corrected distance visual acuity is measured using a ETDRS chart during ophthalmologic examinations at baseline, 1 day, 3 weeks and 3 months

Overall study start date
11/10/2011

Completion date
30/04/2015

Eligibility

Key inclusion criteria
1. Aged between 55 and 85
2. Presence of senile cataract

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
43

Key exclusion criteria
1. Traumatic cataract
2. Extremely dense cataract
3. Subluxated lens
4. Macular or corneal disease

5. Anterior chamber depth shallower than 2.1 mm
6. Pupil dilated less than 5 mm in diameter with 0.2 ml solution of cyclopentolate 0.1% and phenylephrine 1.5%
7. Diabetes
8. Glaucoma
9. Continuous treatment with oral or nasal nonsteroidal anti-inflammatory drugs or steroids
Previous intraocular surgery or retinal photocoagulation

Date of first enrolment
26/09/2012

Date of final enrolment
12/01/2015

Locations

Countries of recruitment
Sweden

Study participating centre
St. Erik Eye hospital
Polhemsgatan 50
Stockholm
Sweden
SE-11282

Sponsor information

Organisation
Eye Foundation (Ögonfonden)

Sponsor details
Synfrämjandets Research Foundation
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Sponsor type
Charity

Website

http://www.ogonfonden.se/kontakt/

Organisation
Stockholm County Council

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Hantverkargatan 45
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Sponsor type
Government

Website
http://www.sll.se/om-landstinget/Information-in-English1/Research/

Organisation
Karolinska Institute

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Solnavägen 1
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Sponsor type
Hospital/treatment centre

Website
http://ki.se/en/about/startpage

Funder(s)

Funder type
Government

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Stockholms Läns Landsting

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

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

Intention to publish date
31/08/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository