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Posterior capsular opacification 9 years after cataract surgery with a hydrophobic acrylic and a hydrophilic acrylic intraocular lenses

Submission date
30/09/2015

Recruitment status
No longer recruiting

Registration date
30/09/2015

Overall study status
Completed

Last Edited
01/10/2015

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
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). There are several different types of intraocular lens that may be used, namely hydrophilic (dissolvable) or hydrophobic (non-dissolvable). This type of surgery is usually very successful, helping to restore vision within a matter of weeks. Posterior capsule opacification (PCO) is a common complication of cataract surgery. When the cataract is removed, a thin, clear membrane is left which holds the intraocular lens in place (lens capsule). When PCO occurs, the lens capsule thickens, causing vision to become cloudy. In most cases, PCO is treated with a painless procedure, where a laser (neodymium: yttrium-aluminium-garnet (Nd:YAG) laser capsulotomy) is used to make an opening in the back of the lens capsule so that light can again reach the retina. Recent evidence suggests that many more cases of PCO develop in the long-run, and the type of intraocular lens used may be linked to its development. The aim of this study is to find out whether hydrophilic or hydrophobic intraocular lens are more prone to developing PCO 9 years after cataract surgery.

Who can participate?
Adults between 60 and 90 years of age who have senile cataract.

What does the study involve?
Participants are randomly allocated into two groups who have either a hydrophilic intraocular lens or a hydrophobic intraocular lens implanted when their cataracts are removed. After nine years, patients in both groups attend a follow up appointment, in which images are taken of their eyes to look for PCO. If any patients have had Nd-YAG laser treatment for PCO, this is noted at the time of the appointment.

What are the possible benefits and risks of participating?
Not provided at time of registration

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?
November 2001 to December 2012

Who is funding the study?
1. Karolinska Institute (Sweden)
2. Stockholms County Council (Sweden)
3. Eye Foundation (Sweden)

Who is the main contact?
Mr Anthony Chang

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
Posterior capsular opacification 9 years after phacoemulsification with the hydrophobic AcrySof SA60AT and hydrophilic BL27 intraocular lenses

Study objectives

A hydrophilic acrylic intraocular lens develops more posterior capsule opacification and has a lower survival rate without Nd:YAG laser capsulotomy than a hydrophobic acrylic intraocular lens 9 years after cataract surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethical review board in Stockholm (Sweden), 07/10/2011, ref: Dnr 2011/1319

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

Health condition(s) or problem(s) studied
Cataract

Interventions
The patients were randomized to one of the two intraocular lenses (IOLs) by selection of an unmarked, opaque envelope from among 120 envelopes containing the name of either the hydrophobic SA60AT IOL or the hydrophilic BL27 IOL. The surgical procedure was the same for all patients and included implantation of an IOL. One group received a hydrophilic IOL and the other group a hydrophobic IOL.
After 9 years, patients attend a follow up appointment where the development of posterior capsule opacification in the two groups is observed and compared. Images of posterior capsule opacification will be obtained and computer software used in order to analyse, calculate and compare posterior capsule opacification between the 2 groups. If earlier Nd:YAG laser capsulotomy was conducted, it was noted at this stage.

Intervention Type

Primary outcome measure
Survival rates without Nd:YAG capsulotomy in hydrophobic and hydrophilic IOL determined from data collected 9 years after surgery.

Secondary outcome measures

Percentage area affected by PCO and PCO severity determined 9 years after surgery using POCOman computer software.

Overall study start date
05/11/2001

Completion date
30/05/2012

Eligibility

Key inclusion criteria
1. Aged 60 to 90 years
2. Presence of senile cataract

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Dilated pupil smaller than 6.0 mm
2. Ocular trauma
3. Traumatic cataract
4. Pseudoexfoliation syndrome,
5. Glaucoma
6. Exfoliation syndrome
7. Corneal pathologies
8. Diabetes mellitus
9. Uveitis
10. Moderate and advanced age-related macular degeneration
11. Those receiving preoperative oral steroid therapy
12. Those who underwent a previous intraocular surgery

Date of first enrolment
22/05/2002

Date of final enrolment
18/03/2004

Locations

Countries of recruitment
Sweden

Study participating centre
St. Erik Eye Hospital
Polhemsgatan 50
Stockholm
Sweden
11282

Sponsor information

Organisation
Ögonfonden

Sponsor details
Ögonfonden / Synfrämjandets Forskningsfond
c/o Fatima Pedrosa-Domellöf
Oftalmiatrik, Umeå universitet
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90185
+46 90 785 13 40
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Sponsor type
Charity

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

Organisation
Stockholm County Council

Sponsor details
Hantverkargatan 45
Stockholm
Sweden
10422
+46 70 737 44 66
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Sponsor type
Government

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

Organisation
Karolinska Institute

Sponsor details
Solnavägen 1
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17177
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Sponsor type
University/education

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Karolinska Institute

Funder Name
Stockholm County Council (Stockholm Läns Landsting)

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Eye Foundation (Ögonfonden)

Results and Publications

Publication and dissemination plan
Publication in a peer reviewed journal.

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository