

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/10/2015	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Mr Anthony Chang

Contact details

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11282

Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)**

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

Key secondary outcome(s)

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

Completion date

30/05/2012

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Organisation

Stockholm County Council

Organisation

Karolinska Institute

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository