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Corneal Glue Study: effect of corneal adhesive on preventing fluid ingress after cataract surgery

Submission date
13/01/2013

Recruitment status
No longer recruiting

Registration date
25/02/2013

Overall study status
Completed

Last Edited
30/06/2014

Condition category
Ear, Nose and Throat

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

Plain English summary of protocol

Background and study aims
Cataract surgery is the most commonly performed operation undertaken in the NHS. The high success rate has led to high patient expectations and low tolerance for complications. The most serious complication is an infection inside the eye following surgery, termed endophthalmitis. The mechanism by which this infection occurs is due to inoculation of ocular surface bacteria into the eye during or after surgery through one of the surgical wounds. Although it occurs very rarely, its visual consequences are devastating. Cataract surgery has developed to the stage where standard practice no longer involves suturing the wounds shut. Instead clear corneal wounds are constructed in such a way that they are self-sealing. This practice allows quicker visual rehabilitation, less surgically induced astigmatism (blurred vision), improved patient comfort and fewer post-operative visits. Recently studies assessing the three dimensional architecture of these wounds post-operatively have found that whilst appearing not to leak at the end of the surgery, many of these wounds may be found to gape (break open) and allow the ingress of fluid after surgery. This seems to be particularly so when the patient blinks and produces a transient reduction in intraocular pressure. New surgical adhesives have recently come to market designed to seal surgical wounds without having the drawbacks of corneal sutures. Whilst they are specifically licensed for this purpose, only a few studies showing their efficacy have been conducted. Our study aims to determine whether a significant correlation exists between wound morphology and fluid ingress (entering in) and whether the application of a corneal adhesive at the end of surgery eliminates fluid ingress.

Who can participate?
Any patient over 45 undergoing routine cataract surgery at Whipps Cross Hospital.

What does the study involve?
All patients will have standard cataract surgery. At the end of surgery, half of those patients whose surgical wounds are found to be self-sealing (the vast majority) will be chosen at random to either have their wounds glued or not. The tissue glue is for the wound on the surface of the eye only and is not to glue the eyelids together. For both groups a drop of fluid (Typtan blue dye) will be placed on the eye at the end of the surgery. This will be left for 2 minutes. The eye

will then be washed and then a sample will be taken to see if any of the dye has leaked through your surgical wounds. This process takes about an extra 3 minutes. Tryptan blue dye is safe and used inside the eye by most surgeons internationally. Some use it on virtually every case with other surgeons reserving it for for more difficult cases to aid visualisation of the cataracts capsule. We will then do some scans (which are like high resolution photographs) about an hour after the operation and again at your two post-operative visits to see what effect the glue (or absence thereof) has had. The first of these visits is a review 1 day after surgery which is sometimes needed whether you are involved in the study or not. The second at 1 week is standard practice.

What are the possible benefits and risks of participating?
There are no individual benefits to be derived from being involved in this study. However, we do hope the results of the study may be of interest to eye surgeons internationally. We suspect that having the glue will reduce the chances of fluid entering the eye after surgery. We cannot be sure until our study is over but, should this prove correct, we might infer that using glue could help reduce the risk of having a post-operative infection. The surgery will be very slightly longer - i.e. around 3-5 minutes. The glue used (OcuSeal®) is a synthetic tissue adhesive designed to provide structural support and form a protective barrier for surgical wounds. Most people undergoing cataract surgery report a foreign-body sensation, or grittiness in the eye for a few days following surgery. This has been reported as being much less noticeable with the use of the glue but it does remain a possibility. Should the glue need to be removed, this is easily performed in clinic. There is a very small risk of having an allergic reaction to the tissue glue or the Tryptan blue. This might be in the form of a red eye, an itchy rash and in extremely rare circumstances facial or throat swelling, hives, or difficulty breathing. The latter would be recognised in hospital and the team are trained how to handle such a circumstance. Talk to any of the team should you have any of the symptoms mentioned. Any other risks are as per those for any cataract operation and will be discussed with you separately.

Where is the study run from?
Whipps Cross Hospital (UK).

When is the study starting and how long is it expected to run for?
The study will begin in February 2013 and will run until July 2013.

Who is funding the study?
Whipps Cross Hospital (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11/LO/0138

Study information

Scientific Title
Corneal Glue Study: effect of corneal adhesive on preventing fluid ingress after cataract surgery a randomised control trial

Acronym
Corneal Glue Study

Study objectives
Vision blue enters the eye when ocuseal glue is not used. If vision blue can enter the eye ocular contaminants can enter the eye and potentially cause endophthalmitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National research ethics service: NRES Committee London-Central, ref:11/LO/0138

Primary study design
Interventional

Study design
Randomised control trial

Study type(s)
Treatment

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

Interventions
Randomisation of patients:
All patients will undergo routine cataract surgery. At the end of routine surgery the corneal wound will be assessed for an obvious leak. If a leak is found the patient will have a corneal suture placed in line with current established practice.

The wounds that are not actively leaking will be randomised into two groups. Group A will undergo no intervention as is current practice and Group B will have the corneal wounds sealed with the biodendrimer adhesive. Groups will be allocated based on random block sequence of groups of 20 patients. The patients will be not blinded to the treatment arm. The technician performing the spectrophotometry will be blinded to the treatment arms.

Measurement of fluid ingress:
After surgery is complete 0.5 ml of 0.125% trypan blue dye will be instilled on the surface of the eye and the speculum removed. The patient will be allowed to blink as normal.

After 2 minutes the speculum will be replaced and 50 ml of saline used to irrigate residual dye from the ocular surface.

A sample of 0.1 ml of aqueous will be aspirated from the anterior chamber and the concentration of trypan blue dye will be measured using spectrophotometry.

Assessment of corneal architecture using OCT:
The patient will undergo non-contact corneal optical coherence tomography at 1 hour, 1 day and 1 week post-operatively. It involves looking at a fixation light whilst an infrared spectrum light is used to scan the cornea and construct a series of cross-sectional profiles. The Optivue Fourier domain OCT with the RTVue 4.0 software module has a resolution of greater than 10 microns, which is more than sufficient to assess the morphological parameters we are interested in.

At each visit the patients will have their vision and intraocular pressures measured and the wounds will be assessed for leakage using the Seidels test with 2% fluorescein in keeping with current standard practice.

Patients will be seen post-operatively at 1 hour, 1 day and 1 week for pressure check and OCT.

Controls
Three patients will have 0.5 ml of trypan blue instilled on the ocular surface prior to any incisions or surgery. This will be left for 2 minutes prior to being irrigated with 50 ml normal saline. A sample of 0.1 ml of aqueous will be taken from the standard side-port incision to confirm that no dye can enter though an intact cornea and to establish a baseline for results considered to be secondary to contamination.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Corneal wounds wound be described as gaping internally, gaping externally, open or closed based on morphological characteristics.
2. A log of aqueous trypan blue concentration would be used as a marker for ingress.

Measured at 1 hour, 1 day and 1 week post surgery.

Key secondary outcome(s)
Patient symptoms post-operatively measured at 1 hour, 1 day and 1 week post surgery.

Completion date
02/07/2013

Eligibility

Key inclusion criteria
1. Fit and well
2. Uncomplicated cataract surgery
3. Male and female patients over 45 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any patient regarded as having clinically significant blepharitis (contraindication to use of biodendrimer glue)
2. Any patient requiring a general, subtenons or peribulbar anaesthetic
3. Any patient requiring intraoperative trypan blue for capsular visualization
4. Any patient who has an intraoperative complication including capsular rupture, zonular dehiscence, suprachoriodal haemorrhage and vitreous loss
5. Any patient who is found to have an actively leaking wound at the end of surgery
6. Patients aged 45 or younger
7. Patients having undergone previous surgery (i.e., vitrectomy, glaucoma filtration surgery)
6. Patients with pre-existing corneal disease (i.e., keratoconus, Fuchs endothelial dystrophy)
8. Patients who lack the capacity to consent for cataract surgery (i.e., those who would need a consent form 4 or consultant consent signed for them in their best interests)

Date of first enrolment
02/02/2013

Date of final enrolment
02/07/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Whipps Cross Hospital
London
United Kingdom
E11 1NR

Sponsor information

Organisation
Whipps Cross University Hospital (UK)

ROR
https://ror.org/016vdk046

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Whipps Cross Hospital (UK) - Department of Ophthalmology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2014		Yes	No