CLINICAL COMPARISON OF INTRACAMERAL CEFUROXIME VERSUS INTRACAMERAL MOXIFLOXACIN FOR PROPHYLAXIS AGAINST POSTOPERATIVE ENDOPHTHALMITIS IN CATARACT SURGERY PATIENTS

A Thesis

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by

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ABSTRACT

Problem: Cataract removal surgery is one of the most common operative procedures performed. While the overall rate of postoperative endophthalmitis is low, the high number of procedures translates that low percentage of occurrence into thousands of patients affected by serious complications that could result in loss of eyesight, permanently decreasing quality of life. **Methods:** Peer-reviewed articles were found that described decreased rates of postoperative endophthalmitis with the use of various perioperative and intraoperative antibiotic regimens. **Results:** Prophylactic use of antibiotics is widespread practice; however, there are no standardized guidelines for best practice. Recent studies show decreased rates of postoperative endophthalmitis with intracameral antibiotics, with cefuroxime and moxifloxacin being the two most commonly used. **Conclusions:** Use of a prophylactic intracameral antibiotic decreases the rate of postoperative endophthalmitis in cataract surgery patients. Intracameral antibiotic prophylaxis should be implemented as a standard of care. Further studies regarding the efficacy of different intracameral antibiotics would contribute to defining best practice recommendations in preventing postoperative endophthalmitis in cataract surgery patients.

BIOGRAPHICAL SKETCH

Kimberly Grady is a candidate for a Master of Science in Health Sciences degree in the Physician Assistant Program at the Weill Cornell Graduate School of Medical Sciences. She received her Bachelor's degree in Biology from Willamette University in 2007. Prior to her graduate studies, Kimberly worked in outpatient eye surgery.

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REVIEW OF THE LITERATURE

1.1 INTRODUCTION

Vision is controlled by different parts of the eye, notably the cornea, iris, lens, and retina. The cornea is the "window" to the eye that first refracts light, the iris regulates how much light enters the eye through the pupil, the lens allows for near and far accommodation in addition to further refracting and focusing light, and the retina contains photoreceptors that transmit signals to the visual cortex of the brain via the optic nerve.[1] Of the many diseases and conditions that can affect each part of the eye and reduce vision, cataracts are the leading cause of blindness worldwide.[2]

A cataract is an opacity of the intraocular lens that may be either congenital or acquired. The intraocular lens is composed of water and crystalline proteins, surrounded by a thin capsule and suspended by the ciliary zonules in the posterior chamber of the eye behind the iris.[1] Acquired cataracts may be related to one or more conditions which can include age, genetics, ultraviolet light exposure, uveitis, steroid use, or trauma. Over time, cataracts mature to become significant enough to lead to visual impairment or blindness if not treated.

The definitive treatment for a cataract is cataract extraction, usually with intraocular lens implantation, and is a commonly performed surgical procedure with the goals of improvement in visual acuity and prevention of blindness. Recent advances in cataract surgery include utilization of femtosecond lasers, extracapsular

cataract extraction by phacoemulsification, and multifocal or astigmatism correcting intraocular lens (IOL) implantation.

A postoperative infection in the eye, or postoperative endophthalmitis, is a serious potential complication of cataract surgery that may result in blindness or even loss of the eye. Postoperative endophthalmitis may be caused by a break in aseptic technique, contaminated supplies or instruments, prolonged surgical time, surgical complications, or postoperative contamination of the wound. The current standard of care for prevention of postoperative endophthalmitis involves a preoperative prep with topical iodine. The use of various perioperative antibiotic eye drop regimens is routine, but the publication of the 2007 European Society of Cataract and Refractive Surgery (ESCRS) trial[3] results showed a clear benefit of intracameral antibiotic use with a 4.92-fold increase (95% confidence interval, 1.87-12.9), in incidence of postoperative endophthalmitis without use of intracameral cefuroxime.

Several studies have been published since the ESCRS trial[4-12] to both evaluate the safety of intracameral antibiotics and determine the most effective antibiotic and dose concentration. Currently, intracameral cefuroxime and moxifloxacin appear to be the most widely used prophylactic intracameral antibiotics and there are several studies evaluating each of their uses.[3-11] However, there are few studies to be found that compare their uses directly and no consensus or uniform guidelines on best intracameral antibiotic use.[11,13]

1.2 METHODS

The Weill Cornell Medical Library online was utilized to search the PubMed database to obtain articles from peer-reviewed journals. Search terms used included "intracameral antibiotics" and "intracameral cefuroxime" as well as "intracameral antibiotics" and "intracameral moxifloxacin". Articles were excluded based on the following criteria: articles published over five years ago with the exception of those that contributed significantly to the topic or have been deemed landmark studies, lack of topic relevance including articles that do not involve clinical or laboratory evaluation of intracameral antibiotic safety and/or use, multiple articles that focused on the same topic with smaller or older studies being excluded, and unavailability of full text article online.

1.3 RESULTS

Overall, 133 articles were found in the PubMed search. Initial results for the search "intracameral antibiotics" and "intracameral cefuroxime" yielded 81 articles. Initial results for the search "intracameral antibiotics" and "intracameral moxifloxacin" yielded 41 articles. Initial results for the search "intracameral cefuroxime" and "intracameral moxifloxacin" yielded 11 articles. Several articles were not included because they were repetitive with smaller or older studies being excluded, independent, small-scale clinical trials designed to evaluate and confirm the

results of the landmark 2007 ESCRS study. Ultimately, 9 of the articles were utilized for analysis.

1.4 DISCUSSION

The articles found for analysis can be categorized by evaluation of the safety and efficacy of intracameral cefuroxime, the safety and efficacy of intracameral moxifloxacin, or the safety and efficacy of intracameral use of both cefuroxime and moxifloxacin.

Articles that evaluate the safety and efficacy of intracameral cefuroxime use

The European Society of Cataract and Refractive Surgery (ESCRS)[3] results clearly showed a statistically significant benefit to administering intracameral cefuroxime. The benefit was so great (4.92-fold increase, 95% confidence interval, 1.87-12.9, in incidence of postoperative endophthalmitis without use of intracameral cefuroxime) that the study was adapted from the planned inclusion of 35,000 patients to less than 17,000 because the ESCRS data monitoring committee came to the conclusion that it would be unethical to continue withholding prophylactic intracameral cefuroxime treatment from future study participants in the levofloxacin or no antibiotic groups. With results that so strongly indicated the use of intracameral cefuroxime, this study provided a well-supported answer to the question of whether or not prophylactic intracameral antibiotic use is of benefit in preventing the occurrence of postoperative endophthalmitis in cataract surgery patients.

A 2010 randomized controlled study by Lam et al[7] investigated the safety of the prophylactic use of three different cephalosporins in cataract surgery. Cefazolin, cefuroxime, ceftazidime or normal saline was injected intracamerally at the end of cataract surgery and safety outcomes were measured by central endothelial cell density and retinal center point thickness preoperatively and three months postoperatively. The authors found no statistical differences in central endothelial cell density and retinal center point thickness between eyes that received any of the cephalosporins or normal saline beyond the expected effects of a normal cataract surgery.

A 2013 report details the institution of intracameral cefuroxime at an English hospital and the protocol put in place for patients with a history of penicillin allergy.[10] While this study is small and simple in design, it offers valuable information regarding use of cefuroxime in patients with a history of allergy to penicillin, a major drawback and source of hesitation for clinicians in administration of prophylactic intracameral cefuroxime. Fifty patients with a history of penicillin allergy that was not suggestive of anaphylaxis received intracameral cefuroxime with no adverse reactions.

Articles that evaluate the safety and efficacy of intracameral moxifloxacin use

An in vitro study by Kernt et al[6] aimed to investigate the safety of intracameral moxifloxacin on human ocular cells. The authors note the limited amount of data on prophylactic intracameral antibiotic administration, and are particularly interested the safety of intracameral moxifloxacin on ocular cells. Effects of moxifloxacin, 10-750 mcg/ml, were evaluated after 24 hours of exposure in the setting of induced stress and inflammation on human corneal endothelial, trabecular meshwork, and retinal pigment cells. Toxicity was assessed by cell survivability rate and cell viability was done by

microscopy count. Results revealed no toxicity on corneal endothelial, trabecular meshwork, or retinal pigment cells at moxifloxacin concentrations up to 150 mcg/ml and support the safe use of prophylactic intracameral moxifloxacin to prevent postoperative endophthalmitis.

A prospective, randomized, controlled study by Lane et al[8] aimed to evaluate the safety of prophylactic intracameral moxifloxacin use in cataract surgery to prevent postoperative endophthalmitis. Safety was evaluated preoperatively and postoperatively for 3 months and included evaluation of visual acuity, intraocular pressure, endothelial cell counts, corneal pachymetry (thickness), corneal clarity and edema, and anterior chamber cells and flare. Results showed no statistical difference in optical tomography between the test and control groups preoperatively or at 3 months postoperatively. Results also revealed no statistical difference in any of the safety parameters at postoperative day 1, 2 to 4 weeks, or 3 months. There were no study-related adverse events in either group. Results support the safety of intracameral use of 250 mcg moxifloxacin for prophylaxis against postoperative endophthalmitis.

A cohort study by Galvis et al[4] compared the rates of postoperative endophthalmitis before and after instituting use of intracameral moxifloxacin. Notably, this study evaluated the outcomes of a single surgeon, minimizing variability in perioperative surgical preferences and surgical technique. While the total number of eyes in the study was 2332 (1056 without intracameral moxifloxacin and 1618 with intracameral moxifloxacin), the results were not statistically significant. There was only 1 case of endophthalmitis in the group that did not receive intracameral moxifloxacin, and no cases in the group that did receive intracameral moxifloxacin.

The authors of the study note that to achieve statistically significant results the study would need to include 21,000 eyes treated with intracameral moxifloxacin and plan to continue the study to confirm the assumed trend of decreased postoperative endophthalmitis with intracameral moxifloxacin injection.

A retrospective cohort study by Matsuure et al[9] aimed to report endophthalmitis rates after cataract surgery and the incidence of complications after intracameral moxifloxacin injection. Nineteen clinics in west Japan participated in a retrospective survey of the 4 years before and after use of intracameral moxifloxacin and the number of cases of endophthalmitis within 1 month after surgery. The authors found 8 incidences of endophthalmitis in 15,958 cases prior to moxifloxacin injection, and 3 incidences of endophthalmitis in 18,794 cases after the addition of moxifloxacin injection.

Matsuure et al note widespread use of intracameral antibiotics in Europe after the 2007 ESCRS study, but highlight that while growing in practice it is not yet common outside of Europe. When intracameral moxifloxacin is considered, there are even fewer studies, especially clinically or on a large scale. While this study was conducted on a large scale, not only was it retrospective, but also drew on data from several centers with varying protocols for intracameral moxifloxacin injection. The moxifloxacin dose administered varied from 50 mcg/ml to 500 mcg/ml, and one center injected the moxifloxacin into the continuous irrigation bottle as opposed to a single injection at the end of surgery. While a good start, it would be recommended to develop a large-scale prospective study on the use of intracameral moxifloxacin with uniform protocol.

Articles that evaluate the safety and efficacy of intracameral cefuroxime and moxifloxacin use

An in vitro study by Haruki et al[5] aimed to investigate and compare the toxic effects of moxifloxacin, cefuroxime and levofloxacin on corneal endothelial cells to determine safe intracameral concentrations. Toxicity was measured based on cell damage, cell viability, and cytokine secretion. The authors found that toxicity from cefuroxime required high doses (500 mcg/ml) and occurred at 24 hours. Toxicity from moxifloxacin also required high doses (350 mcg/ml for trabecular meshwork and retinal pigment cells) and occurred at 6 hours. The toxicity findings for levofloxacin were similar to moxifloxacin, but the minimum inhibitory concentration (MIC) for levofloxacin is much higher than moxifloxacin. The authors conclude that, while toxic at high doses, moxifloxacin is a viable alternative to cefuroxime and recommended for prophylaxis at under 500 mcg/ml.

Shorstein et al[11] published the first large-scale study in the United States in 2013 confirming decreased rates of endophthalmitis with the use of intracameral antibiotics. The primary intracameral antibiotic utilized was reconstituted cefuroxime in 84% of cases and moxifloxacin in 15% of cases. Over a 5-year period intracameral antibiotic use increased from 11% to 100% and the patients who received intracameral antibiotics had a 13-fold lower rate of postoperative endophthalmitis. However, in spite of overwhelming evidence in support of the use of prophylactic intracameral antibiotics, the study authors acknowledge that an ecological timescale study is better suited to provide supportive evidence, and that a randomized controlled trial would be better to establish causation.

1.5 CONCLUSION

Currently there are multiple clinical studies that evaluate the safety and efficacy of the prophylactic use of either intracameral cefuroxime or intracameral moxifloxacin for preventing postoperative endophthalmitis, as well as laboratory studies that compare the safety and efficacy of both cefuroxime and moxifloxacin. However, there has yet to be a large-scale direct clinical comparison of the two antibiotics. In light of the literature reviewed, the next step in defining the best use of intracameral antibiotics would be to design a large-scale clinical study to directly compare the use of intracameral cefuroxime versus the use of intracameral moxifloxacin for evaluation of the lowest incidence of postoperative endophthalmitis.

RESEARCH PROPOSAL

2.1 ABSTRACT

Problem: Cataracts are the leading cause of blindness worldwide, and cataract surgery is one of the most common operative procedures performed. The number of cataract surgeries continues to increase as populations across the globe age, eg, Americans and the baby boomer population. While the overall rate of postoperative endophthalmitis is low, the high number of procedures translates a low percentage of occurrences into thousands of patients affected by serious complications that could cost them their eyesight, permanently decreasing their quality of life. **Purpose:** The purpose of this study will be to evaluate the efficacy of intracameral cefuroxime versus intracameral moxifloxacin in preventing postoperative endophthalmitis in cataract surgery patients to help define the best use of prophylactic intracameral antibiotics. **Research Questions:** Is there a difference in the rate of postoperative endophthalmitis after cataract surgery when using antibiotic prophylaxis with intracameral cefuroxime versus intracameral moxifloxacin? Is the difference in postoperative endophthalmitis rates after cataract surgery with prophylactic intracameral cefuroxime versus intracameral moxifloxacin statistically significant? **Methods:** The subjects of this study will be adult patients undergoing clear corneal incision cataract surgery without any additional planned procedures. The patients will be enrolled from participating hospitals and surgery centers and be randomized into one of two groups. **Outcomes:** The outcome of this study will provide evidence for whether or not there is a benefit

provided by use of one intracameral antibiotic over the other. **Benefit:** This study will help define standards for best use of intracameral antibiotic use for prophylaxis against postoperative endophthalmitis in cataract surgery patients. It will potentially reduce the rates of postoperative endophthalmitis and thereby further minimize the number of patients who suffer from vision or globe loss after cataract surgery.

2.2 AIMS

2.2.1 Project Overview

This study will assess the clinical efficacy of intracameral cefuroxime versus the clinical efficacy of intracameral moxifloxacin in prevention of postoperative endophthalmitis in cataract surgery patients. Past studies have demonstrated the safety and efficacy of prophylactic use of both intracameral cefuroxime and intracameral moxifloxacin; however, there is no clear consensus on the superiority of one antibiotic over the other and there has yet to be a large-scale direct clinical comparison.

2.2.2 Research Questions

1. Is there a difference in the rate of postoperative endophthalmitis after cataract surgery when using antibiotic prophylaxis with intracameral cefuroxime versus intracameral moxifloxacin?
2. Is the difference in postoperative endophthalmitis rates after cataract surgery with prophylactic intracameral cefuroxime versus intracameral moxifloxacin statistically significant?

2.2.3 Specific Aims

AIM 1: Create a two-armed study to investigate the clinical efficacy of intracameral cefuroxime versus intracameral moxifloxacin in prevention of postoperative endophthalmitis in cataract surgery patients.

AIM 2: Calculate the rates of postoperative endophthalmitis in patients who received intracameral cefuroxime versus intracameral moxifloxacin.

AIM 3: Determine a preliminary best use recommendation for prophylactic intracameral antibiotic administration in cataract surgery patients to prevent postoperative endophthalmitis.

2.2.4 Hypothesis

As a fourth generation fluoroquinolone, moxifloxacin will have better prophylactic coverage than the second-generation cephalosporin, cefuroxime, and have a lower rate of incidence of postoperative endophthalmitis in cataract surgery patients.

Null hypothesis: Neither intracameral cefuroxime or intracameral moxifloxacin will result in a statistically significant lower rate of postoperative endophthalmitis after cataract surgery.

Hypothesis: Intracameral moxifloxacin will have a statistically significant lower rate of postoperative endophthalmitis after cataract surgery than intracameral cefuroxime.

2.3 BACKGROUND AND SIGNIFICANCE

2.3.1 Background

Cataracts may be caused by any number of factors, including age. As advances in medicine continue to increase longevity, a growing number of people will experience a decrease in vision due to cataract formation. Cataract surgery is already the most commonly performed procedure worldwide. Millions of people will have the procedure performed on one or both of their eyes. When there are millions of people who will have a procedure that means there are millions of people who are at risk to

experience a complication from the procedure. Specifically, the risk of consequence in this setting is the incidence of postoperative endophthalmitis in cataract surgery patients. Although the rates of postoperative endophthalmitis are reported to be as low as 0.06-0.25%,[14] the high number of surgeries performed translate into thousands of people who may experience a decrease in visual acuity, total vision loss or even loss of the globe based on sheer numbers.

Although prophylactic use of antibiotics is widely accepted, there are no uniform guidelines or best practice recommendations regarding use of specific antibiotics or routes of administration.[11] Prophylactic antibiotic regimens are selected based on surgeon preference and may include one or more of the following: preoperative eye drops, perioperative eye drops, postoperative eye drops, intraoperative intracameral administration through the irrigation fluid, and subconjunctival injection or intracameral injection at the end of surgery.

Initial studies that demonstrated the benefit of using prophylactic intracameral antibiotics administered intracameral cefuroxime.[3] Subsequent studies have followed that confirm prophylactic administration of intracameral cefuroxime reduced rates of postoperative endophthalmitis.[7,10,11] Intracameral cefuroxime is currently the unofficial prevailing choice for intracameral antibiotic prophylaxis. Recent studies have shown that intracameral moxifloxacin also significantly reduces the rates of postoperative endophthalmitis in cataract surgery patients[4,8,9] and could be a better alternative to intracameral cefuroxime since it has broader spectrum coverage as a fourth generation fluoroquinolone as opposed to a second generation cephalosporin, its antimicrobial properties are concentration-dependent instead of time-dependent,[4,8,14] it

does not require reconstitution and dilution from a powder,[12,14] and eliminates concern regarding beta-lactam hypersensitivity.[10,11,14]

2.3.2 Project Significance

The ability to see is crucial to a person's independence and quality of life. It may be one of the most important factors that affect quality of life since there is no way to make up for its complete loss. A person who is mute may learn to communicate via sign language, a person who loses their hearing or is born deaf may benefit from a hearing aid or cochlear implant, and there are many modalities and options for those who are affected by loss of the use of a limb or loss of a limb.

There are ways to enhance or correct a person's level of vision by use of glasses, contacts or laser surgery. There are ways to preserve a person's level of vision by use of eye drops, shunts or other surgical procedures to decrease intraocular pressure, or laser retinopexy to halt progression of retinal damage. However, there is no way to replace vision once it has been permanently lost. For the thousands of cataract surgery patients who may be affected by permanent decrease in vision or complete vision loss due to complications from postoperative endophthalmitis, determining best practice recommendations for use of prophylactic intracameral antibiotics is necessary in an effort to further reduce the rates of postoperative endophthalmitis and preserve vision and quality of life in as many people as possible.

2.4 PRELIMINARY STUDIES

Not Applicable

2.5 RESEARCH DESIGN AND METHODS

2.5.1 Design

This will be a two-armed, multi-center, randomized control study. Both groups will consist of patients undergoing first or second eye cataract extraction with intraocular lens implant surgery, without any planned additional procedures eg, same day sequential cataract removal, pterygium excision, limbal relaxing incisions or trabeculectomy. Patients who undergo unplanned procedures eg, sulcus lens implantation, posterior capsule tear, vitrectomy or corneal incision closure with suture will remain in the study.

One group will receive 1 mg intracameral cefuroxime, and the other group will receive 250 mcg intracameral moxifloxacin at the end of their cataract surgery. The group that receives intracameral cefuroxime will act as a control group since intracameral cefuroxime was the antibiotic utilized in the ESCRS trial. Additionally, withholding intracameral antibiotic administration would be unethical since the use of intracameral antibiotics has been shown to significantly reduce the rates of postoperative endophthalmitis.

2.5.2 Methods

Study approval from the appropriate institutional review board (IRB) will be obtained prior to proceeding with recruitment of participants. All patients seen by participating attending and/or resident surgeons at selected institutions who meet selection criteria will be approached for participation. Participants will sign IRB-

approved consent for enrollment in the study. Participants will be selected based on the following criteria:

1. Must be diagnosed with a clinically significant atraumatic cataract.
2. Must opt for elective surgery prior to approach for participation.
3. Must be undergoing first or second eye cataract surgery only, no combined procedures.
4. Must be over 18 years of age and have capacity to give consent.
5. Must not have a drug allergy that precludes participation in the preoperative iodine prep, either study group, or topical eye drop regimen.
6. Must not have an open infection of any kind or an infection near the eye.

There are no eligibility requirements related to gender, race, socioeconomic status or sexual orientation and all eligible patients will be approached for participation in this study. Study subjects will be adult patients who are undergoing elective first or second eye clear corneal incision cataract surgery with intraocular lens implantation. Participants will be selected by contacting ophthalmology clinics associated with the New York-Presbyterian hospital system. Patients will be randomized into a study group and receive the assigned intracameral antibiotic—either 1 mg cefuroxime or 250 mcg moxifloxacin— at the end of their cataract surgery. The groups will be matched for age, gender, race and socioeconomic status.

Patients will be followed up at postoperative days 1 and 7 since postoperative endophthalmitis typically presents acutely, and at 28 days as well as 3 months postoperatively since postoperative endophthalmitis may sometimes be seen as late as several weeks following surgery.[15] At each visit clinicians will assess operative eye

appearance, visual acuity, and perform a slit lamp exam to evaluate for postoperative endophthalmitis. Signs and symptoms of postoperative endophthalmitis include decreased visual acuity beyond what is expected for postoperative recovery, corneal edema, eyelid edema, conjunctival hyperemia, anterior chamber cells and flare, loss of red reflex, hypopyon and deep eye pain. In the event that a clinician determines a patient may have signs or symptoms of postoperative endophthalmitis, aqueous and vitreous samples will be collected for culture and sensitivity to differentiate between toxic anterior segment syndrome (TASS) and true endophthalmitis.

2.5.3 Statistical Analysis

Data will be analyzed using an independent samples two-tailed t test. A 95% confidence interval and a statistical significance of $p<.05$ will be used. The statistical power will be 0.8, or 80%.

A priori power analysis was calculated based on reported rates of endophthalmitis of 0.06-0.25%[14] which sets the mean for group 1 at 0.006 and the mean for group 2 at 0.025. The resultant effect size d of 0.038 with an α error probability of 0.05 and power of 0.8 determined a minimum total sample size of 21,744 and group sample size of 10,872.

2.5.4 Limitations

There are several limitations to this study. First is the enrollment of a sufficient number of participants. A priori power analysis requires 21,744 participants, 10,872 in each group. The number of participants that are needed for enrollment is large, but in the context of how commonly performed cataract surgery is and how low the reported rates of endophthalmitis are, it is not unfounded. The requirement of thousands of

study participants is comparable to prior studies on the reduced incidence of postoperative endophthalmitis with use of intracameral antibiotics. The Shorstein et al study[11] included over 16,000 participants and the ESCRS trial anticipated 35,000 participants, and ultimately reached approximately 17,000 due to termination for ethical reasons regarding withholding treatment from the control group.

Anticipated confounding variables include preoperative prep protocol, topical antibiotic regimen, patient compliance with the topical antibiotic regimen, occurrence of TASS, and loss of participants due to removal from study for occurrence of TASS or loss to follow-up. To eliminate and control confounding factors, all participating surgery centers and hospitals will have to meet minimum preoperative prep requirements (eye wash with iodine), the topical eye drop regimen will be unified for the study, results will be calculated with and without topical eye drop regimen compliance based on patient reporting, the occurrence of TASS will be differentiated from postoperative endophthalmitis by culture, cases of TASS will be removed from the study, and loss of participants will be compensated for by ongoing enrollment to meet at least 21,744 participants.

2.5.5 Timeline

IRB approval will be obtained by August 2016. Recruitment will begin in August 2016 with ongoing enrollment into the study. Enrollment will end in August 2018, or when the study has reached at least 21,744 participants. Data collection will be conducted continuously as participants are seen at their follow-up appointments on postoperative days 1, 7, and 28 as well as 3 months postoperatively. The last

postoperative follow-up appointments will be in November 2018. Data analysis and dissemination of findings will be completed by November 2019.

2.5.6 Conclusion

This will be the first two-arm, multi-center, randomized controlled study to directly compare and evaluate the rates of postoperative endophthalmitis in cataract surgery patients who received either prophylactic intracameral cefuroxime or prophylactic intracameral moxifloxacin. Intracameral administration of cefuroxime has become the unofficial standard of intracameral antibiotic prophylaxis in cataract surgery patients, although recent studies also show a decrease in rates of postoperative endophthalmitis in cataract surgery patients with the use of intracameral moxifloxacin. Data obtained from this study may help determine guidelines for best use practice regarding intracameral antibiotic prophylaxis, and subsequently prevent permanent decreases in level of vision or total vision loss for thousands worldwide.

2.6 SUMMARY

In summary, this study hopes to help define the guidelines regarding the prophylactic administration of intracameral antibiotics in cataract surgery patients. The goal is to determine the best means of prophylaxis in order to preserve the sight and quality of life in as many cataract surgery patients as possible. Results obtained would provide ophthalmologists with evidence for the most appropriate intracameral antibiotic protocol for their patients.

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