ESCRS study on antibiotic prophylaxis of endophthalmitis yields positive result

THE European Society of Cataract and Refractive Surgeons have halted recruitment to their two year clinical trial of antibiotic prophylaxis of endophthalmitis after cataract surgery. The study has found that the risk of contracting endophthalmitis following phacoemulsification cataract surgery is significantly reduced by an intracameral injection of cefuroxime at the end of the surgery. By the end of 2005 approximately 16,000 patients had been recruited to the study. The study was recently unmasked after further cases of endophthalmitis may be reported, however it is not expected that this will alter the main conclusion. The study also showed a background rate higher than had been anticipated from a review of reported studies. The use of perioperative levofloxacin eye drops has been associated with a reduction in the observed incidence rate of endophthalmitis, but in this study, the effect is smaller and is not statistically significant.

The ESCRS Study, a partially masked, randomised, placebo controlled, clinical study was conducted at twenty-four ophthalmology units in Austria, Belgium, Germany, Italy, Poland, Portugal, Spain, Turkey and the United Kingdom. Recruitment commenced in September 2003. The clinical study evaluated prospectively the prophylactic effect of intracameral cefuroxime injection and/or intensive perioperative levofloxacin eye drops on the incidence of endophthalmitis following phacoemulsification cataract surgery. After follow-up is completed the study is expected to total 16,000 patients.

It was originally thought that the study would need to recruit 32,000 patients to conclusively demonstrate an effect for either treatment. In January 2006 quarterly analysis of the figures to date carried out by the study’s statistician’s at the University of Stratchclyde clearly indicated a probable beneficial treatment effect. The Data Monitoring Committee recommended that the study be unmasked and found the result to be so clear that recruitment was halted. Two factors aided in this satisfactory outcome. The first is that the background rate of postoperative endophthalmitis in the group receiving neither perioperative levofloxacin nor intracameral cefuroxime was almost twice as high as reported in a review of the literature prior to the study. The background rate is that occurring in the minimal treatment group who received povidone iodine lavage preoperatively for 3 minutes and topical levofloxacin postoperatively for 1 week to prevent wound infection. The second factor was the large size of the effect produced by the use of intracameral cefuroxime. This reduction is in line with results reported by Per Montan and his colleagues in Sweden in their long running retrospective and prospective but uncontrolled study. (See next month’s issue of EuroTimes).

“This confirmation that a potentially blinding complication of postoperative intracocular infection can be reduced five fold should convince surgeons to adopt the use of intracameral cefuroxime as a standard part of the procedure of modern phacoemulsification cataract surgery,” said Mr Peter Barry, chairman and originator of the study.

The rationale and methodology of this study and a short report on the results will be published in the March issue of the Journal of Cataract and Refractive Surgery. More detailed analyses after follow-up is completed will be presented at the XXIV Congress of the ESCRS in London in September 2006.