Brinzolamide/Brimonidine Combination vs Brimonidine 0.2% in the Prevention of IOP Rise After Nd-YAG Laser Capsulotomy

NCT03192826

24 April 2016

Study protocol

This prospective, randomized, double masked comparative study comprised 79 eyes of equal consecutive patients treated with Nd:YAG laser posterior capsulotomy due to PCO after uneventful phacoemulsification cataract extraction with implantation of posterior chamber intraocular lenses (IOL-PC). The research was approved by the Institutional Review Board, and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants. Patients were randomized in 3 groups. The Brimonidine group (n=27) received a commercial preparation of Brimonidine 0.2% (Alphagan, Allergan Pharmaceuticals Ltd, Westport, Ireland). The Brinzolamide/Brimonidine group (n=27) received a commercial preparation of Brinzolamide 1%/Brimonidine 0.2% fixed combination (BBFC) (Simbrinza, Alcon Laboratories Ltd, Hertfordshire, United Kingdom). The Control group (n=25) received artificial tears (Tears Naturale II, Alcon Laboratories A.E.B.E., Athens Greece). Only one eye for each of the patients was enrolled in the study. Randomization was performed using the order of entrance in the study. In all groups the medication was administered as a single drop instillation, approximately 1 hour before Nd:YAG application. Exclusion criteria included patients with a baseline IOP greater than 21mmHg, glaucomatous eyes, intraocular surgery except from uncomplicated cataract surgery, previous photorefractive surgery, active ocular inflammation or infection. Additional exclusion criteria included patients under systemic administration of medication ns known to affect IOP, pregnant or breastfeeding women, and individuals with known hypersensitivity or contraindication to administration of the medications tested. Finally, an IOP increase >20 mmHg from baseline at any time point of the study would require rescue treatment and was considered an exclusion criterion. All patients underwent a complete ophthalmic examination, including Goldmann applanation tonometry. The baseline IOP measurement was performed by a masked investigator (OM) approximately 1 hour before Nd:YAG application, just before instillation of the study medication. Pupillary dilation was performed by the instillation of a single drop of tropicamide 0.5% (Tropixal, Demo SA, Greece). All

capsulotomies were performed by the same surgeon (CG) who was masked to treatment assignment, after application of 1 drop of proparacaine HCl 0.5% eye drops (Alcaine; Alcon Laboratories, Inc. Fort Worth, TX) as anaesthetic. Laser spots were applied through a widefield contact lens until a sufficient -approximately 4mm in diameter- capsule opening had been created. The total number of laser spots and the total amount of energy utilized were recorded. After Nd:YAG treatment all patients were prescribed dexamethasone 0.1% (Maxidex, Alcon Laboratories A.E.B.E., Athens Greece) qid for 1 week. Post Nd:YAG IOP measurements were performed at 1, 3 and 24 hours and at 1 week after capsulotomy, by the same investigator (OM) who had performed the baseline IOP measurements and was masked to the group assignments. Two consecutive IOP measurements were obtained, and the average value was calculated and used for analysis.

Statistical Analysis

The SPSS statistical package version 23.0 (Statistical Package for the Social Sciences, version 23.0, SSPS Inc. Chicago, IL, USA) was used for statistical analysis. Repeated measures ANOVA was used to compare parametric values with Bonferroni post hoc test for within group comparisons. Categorized data were analyzed by the chi-square test and the Bonferroni correction was applied to avoid the risk of committing a type I error for between group comparisons. More precisely, the alpha-level of 0.05 was corrected for multiple comparisons involving the three outcome measures, resulting in an adjusted alpha of 0.017 (0.05/3). Statistical analysis was performed by an investigator blinded to the assignment of patients.