



CATARATA, CÓRNEA, RETINA MÉDICA, GLAUCOMA E
OFTALMOLOGIA PEDIÁTRICA

17:00 | 19:00 SALA NEPTUNO

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18:16

RFP20- SUPERIORITY OF A FIXED COMBINATION OF BRINZOLAMIDE 1% AND BRIMONIDINE 0.2% VS BRINZOLAMIDE 1% OR BRIMONIDINE 0.2% IN PATIENTS WITH OPEN-ANGLE GLAUCOMA

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Introduction: To assess the superiority of brinzolamide 1% and brimonidine 0.2% (BBFC), a fixed combination given twice daily (the approved dosing regimen in the European Union and other countries), as compared to brinzolamide 1% (BRINZ) and brimonidine 0.2% (BRIM) monotherapies in lowering intraocular pressure (IOP) in patients with primary open-angle glaucoma or ocular hypertension. The impact of demographic subgroups on the overall efficacy and safety were also investigated.

Materials and Methods: This was a Phase III, 6-month, prospective, randomized, double-masked, active-controlled, multicentre study (NCT01310777). Patients were randomized 1:1:1 to receive BBFC, BRINZ, or BRIM at 9 am and 9 pm for 6 months. The primary endpoint was mean diurnal IOP change at Month 3 from baseline. Superiority of BBFC over BRINZ or BRIM monotherapy was determined by pairwise t-tests of least squares (LS) means at Month 3. The effect of demographic subgroups such as age, gender, race, diagnosis, baseline IOP, and baseline corneal thickness on the overall study results were assessed.

Results: Of the 559 patients assessed, 193 received BBFC, 191 received BRINZ, and 175 received BRIM. At Month 3, mean change in IOP with BBFC (LS mean \pm SE, -7.9 ± 0.22 mmHg) was superior to that seen with BRINZ (LS mean difference: -1.4 mmHg; $p < 0.0001$) or BRIM (LS mean difference: -1.5 mmHg; $p < 0.0001$). Mean percent IOP reduction was greater with BBFC (-26.7 to -36.0%) compared with BRINZ (-22.4 to -27.9%) or BRIM (-20.6 to -31.3%) across all visits and time points over 6 months. The most common adverse drug reactions with BBFC were ocular hyperaemia, eye pain and dysgeusia. The incidence (n [%]) of serious adverse events (SAEs) was similar between BBFC (5 [3]), BRINZ (2 [1]) or; BRIM (3 [2]). Overall, no differences were observed between demographic subgroups across all treatment groups; no conclusions could be drawn due to variations in sample sizes across the subgroups.

Conclusions: After 3 months of treatment, twice-daily administration of BBFC provided superior IOP-lowering efficacy compared to BRINZ or BRIM monotherapy, in patients with open-angle glaucoma or ocular hypertension. The safety profile of BBFC was consistent with the known safety profiles of BRINZ and BRIM. Definitive conclusions on the impact of demographic subgroups could not be made; however, the safety and efficacy within the predefined subgroups were similar to the overall study findings.