CATARATA, CÓRNEA, RETINA MÉDICA, GLAUCOMA E OFTALMOLOGIA PEDIÁTRICA

17:00 | 19:00 SALA NEPTUNO

Coordenador: António Melo
Mesa: Maria do Céu Brochado Pinto, José Pedro Silva, Cristina Tavares

18:20

RFP21- FIXED COMBINATION OF BRINZOLAMIDE 1% / BRIMONIDINE 0.2% VS UNFIXED BRINZOLAMIDE 1% AND BRIMONIDINE 0.2% IN OPEN-ANGLE GLAUCOMA OR OCULAR HYPERTENSION

Luisa Ribeiro
(Association for Innovation and Biomedical Research on Light and Image (AIBILI))

Introduction: To assess whether brinzolamide 1% (BRINZ) and brimonidine 0.2% (BRIM) administered as a fixed combination (BBFC) twice daily (the approved dosing regimen in the European Union) was non-inferior to unfixed BRINZ and BRIM dosed concomitantly (BRINZ + BRIM) in lowering intraocular pressure (IOP) in patients with primary open-angle glaucoma or ocular hypertension. The impact of demographic subgroups on overall study efficacy and safety results was also assessed.

Materials and Methods: In this 6-month, randomised, double-masked, multicentre, Phase III study (NCT01309204), patients were randomised 1:1 to receive BBFC or BRINZ + BRIM twice daily at 9 am and 9 pm for 6 months. The primary endpoint was the mean diurnal IOP change at Month 3 from baseline. Non-inferiority was established if the upper limit of 95% confidence interval (CI) of the between-group difference in least squares (LS) mean change from baseline to Month 3 was <1.5 mm="" hg="" the="" impact="" of="" demographic="" subgroups="" such="" as="" age="" gender="" race="" diagnosis="" baseline="" iop="" and="" corneal="" thickness="" on="" overall="" study="" results="" was="" assessed="" using="" a="" pre-planned="" analysis="" p="">

Results: Of the 831 patients assessed per protocol, 420 received BBFC and 411 received BRINZ + BRIM. At Month 3, the mean change in IOP with BBFC (LS mean ± standard error [SE], −8.5 ± 0.16 mmHg; −32.2%) was non-inferior to that with BRINZ + BRIM (−8.3 ± 0.16 mmHg; −31.3%; mean between-group difference, −0.1 mmHg; 95% CI, −0.5 to 0.2 mmHg). The mean percent IOP reduction was similar with both BBFC and BRINZ + BRIM at all visits and time points over 6 months. Mean IOP was similar at all visits: BBFC, 9 am range, 19.2–19.7 mmHg; 11 am range, 16.0–16.4 mmHg; BRINZ+BRIM, 9 am range, 19.1–19.5 mmHg; 11 am range, 16.2–16.5 mmHg. The most common adverse events (AEs) with BBFC were ocular hyperaemia, eye pain and dysgeusia. The incidence (n [%]) of serious adverse events was similar between BBFC (11 [2.4%]) and BRINZ + BRIM (7 [1.6%]). Ocular hyperaemia was the most common treatment-related ocular AE, reported in 3.5% and 3.9% of the patients in BBFC, and BRINZ + BRIM, respectively. Definitive conclusions on the impact of demographic subgroups, such as age, gender, race, diagnosis, baseline IOP and baseline corneal thickness on IOP-lowering efficacy could not be drawn. However, in general, the efficacy of BBFC was similar to that of BRINZ + BRIM in each subgroup.

Conclusions: After 3 months, the IOP-lowering efficacy of BBFC was non-inferior to that of BRINZ + BRIM 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 drawn; however, the safety and efficacy within the pre-defined subgroups were similar to the overall study findings.