

R1 R2 R3 PG0 PG1 Estagiário Tecnólogo PIBIC

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Service (sector)
Glaucoma

Nº CEP

Efficacy of Isopropyl Unoprostone and Timolol Maleate in Chronic Open Angle glaucoma or Ocular Hypertension. A Comparative, Double-Masked, Randomized Clinical Trial.

Paranhos, Jr., A.; Duarte, B.,F.; Moura, C.R.R.; Rocha, L.C.; Villaça, V.; Costa, V.P., Mello, P.A.A.

Objective: To evaluate the ability of Isopropyl Unoprostone (IU) in maintaining the intraocular pressure of patients previously receiving Timolol Maleate TM 0,5%..

Methods: Phase III randomized, double-masked multicentre, parallel-group comparison of IU and TM 0.5% BID in 39 subjects with chronic open-angle glaucoma or ocular hypertension. Prior to randomization, all subjects were pre-treated with TM 0.5% for 2 weeks. Patients were then randomized to either TM or IU BID for 6 weeks. IOP was measured 2 hours following the morning instillation (approximately at 10:00 AM). Statistical analyses were done with two-Way ANOVA, ANCOVA and the paired Student's t-test on the intent-to-treat population.

Results: 39 subjects completed the study, 19 on IU and 20 on TM 0,5%. Mean IOPs prior to the randomization in both groups were not significantly different ($p=0.147$). At Week 4, mean IOP change from baseline for subjects randomized to IU was lower than the mean change from baseline for subjects randomized to TM 0.5% (-0,48 mmHg vs. +0.81 mmHg, respectively; $P= 0.025$). At week 6, differences in mean IOP change from baseline were not statistically significant between the groups ($P=0.606$).

Conclusion: At the end of the 6-week treatment period, IU and TM 0,5% both maintained similar IOP-lowering effect.