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A COMPARATIVE, RANDOMIZED, DOUBLE BLIND, PARALLEL GROUP AND NON CROSSOVER MULTICENTRIC CLINICAL STUDY WITH BEPOTASTINE BESILATE OPHTHALMIC SOLUTION VS. OLOPATADINE HYDROCHLORIDE OPHTHALMIC SOLUTION IN SUBJECTS SUFFERING FROM ALLERGIC CONJUNCTIVITIS.

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BACKGROUND
This study was designed to evaluate the efficacy, safety and tolerability of Bepotastine Besilate Ophthalmic Solution 1.5% w/v (Arm A) Vs. Olopatadine Hydrochloride Ophthalmic Solution 0.1% w/v (Arm B) in Subjects suffering from Allergic Conjunctivitis. The main objective of the study was to compare subjects-perceived relief from the symptoms of ocular itching, conjunctival redness, tearing (watery eyes), eyelid swelling and eye discharge.

METHOD
It was a comparative, randomized, double blind, parallel group, non-crossover, active control multi-centric clinical trial conducted in 12 centers across India in subjects with signs and symptoms of allergic conjunctivitis. The recruitment has been started from Dec 31, 2014 to Nov 24, 2015. Total 200 patient (aged 10 – 60 years) were randomized with 99 enrolled in Arm A and 101 in Arm B.

All the subject were advised to instil one drop twice a day into the affected eye of either Bepotastine or Olopatadine as per randomization. The treatment continued for 21 days with periodic follow-up on 7th, 14th and 21th day from start of treatment.

RESULTS
The current study showed the Mean change in ocular itching and Conjunctival Redness Score from baseline to visit 4 for Bepotastine and Olopatadine as (-2.5,-2.5 P=0.8793) & (-2.5,-2.3 P= 0.2249) respectively. There were 08 clinical adverse events reported (Bepotastine: 03, Olopatadine: 05) which were mild in nature.

CONCLUSION
Bepotastine Besilate Ophthalmic Solution is equivalent in all primary efficacy variables and has equal efficacy of improving the clinical features of Allergic Conjunctivitis when compared with Olopatadine and as safe as Olopatadine.

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