A randomized, controlled study of the efficacy and safety of a new eyedrop formulation for moderate to severe dry eye syndrome

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Abstract

Purpose: This study compared the efficacy and safety of hyaluronic acid (HA)-trehalose, a new eyedrop containing trehalose (a natural bioprotectant) and HA, to an established formulation containing only HA.

Methods: This was a phase III, randomized, active-controlled, investigator-masked, multicenter study in France and Tunisia. In all, 105 adult patients (≥18 years) with moderate to severe dry eye disease (DED) received either HA-trehalose (n = 52) or HA (n = 53) 3-6 times per day for 84 days. The primary efficacy variable was the Oxford grading score at day 35. A questionnaire on dry eye and symptoms, Schirmer test, tear break-up time, conjunctival hyperemia, and global performance were assessed as secondary efficacy criteria at baseline, day 35, and day 84. Safety assessments were standard.

Results: Noninferiority of HA-trehalose to HA for keratoconjunctivitis sicca assessed by Oxford grading score was demonstrated at day 35. For the secondary efficacy parameters, reductions in dry eye questionnaire classes of none or mild at day 84, dry eye symptoms of stinging, itching, and blurred vision at day 35, and investigator (days 35 and 84) and patient assessments (day 35) of global performance were significantly better for HA-trehalose. There were no clinically meaningful differences between groups for the other secondary criteria. Both treatments were well-tolerated, and there were fewer ocular symptoms upon instillation and fewer adverse events for HA-trehalose than for HA.

Conclusions: Hyaluronic acid-trehalose is effective and safe, with better patient satisfaction, than existing HA-only eyedrops particularly from the first month of treatment, and offers a therapeutic advancement in the treatment of moderate to severe DED.

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