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A randomized, placebo-controlled trial to evaluate the efficacy and safety of novel mixtures of 0.01% or 0.02% cyclosporine A with 3% trehalose in dry eye syndrome

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Trehalose has been known to stabilize bilipid membranes and proteins against desiccation, and to have a protective effect against desiccation and oxidative insult in the mammalian eye, which has been made into some tear preparations. In this trial, the efficacy and safety of a novel mixture of 0.01% or 0.02% cyclosporine A(CsA) with 3% trehalose in dry eye were analyzed. Dry eye patients with corneal staining score more than 2 were randomly assigned to receive mixture of 3% trehalose and topical 0.01% (low dose treatment) or 0.02% (high dose treatment) CsA, or placebo to be administered twice daily for 12 weeks. The primary efficacy outcome was a change from baseline in corneal fluorescein staining scores at week 12, and changes at week 4 and 8 were reported as secondary endpoints. Additional endpoints included score changes from baseline in conjunctival staining, strip meniscometry, tear breakup time(TBUT), Standard patient evaluation of eye dryness questionnaire(SPEED) at week 4, 8 and 12 and ratio of 100% clearance in corneal staining. At week 12 of treatment, corneal staining scores were improved in patients treated with high-dose treatment, with significant difference compared to the placebo treatment (p=0.0361). There was no significant difference between low-dose treatment and placebo in corneal and conjunctival staining, strip meniscometry, TBUT, SPEED at week 4, 8 and 12. There were no significant difference between high-dose treatment and placebo in corneal staining at week 4, 8, conjunctival staining, strip meniscometry, TBUT, SPEED at week 4, 8 and 12. Ratio of 100% clearance in corneal staining were 53.13% in placebo, 55.17% in low-dose treatment, 78.57% in high-dose treatment. High-dose treatment is shown to alleviated corneal staining signs of dry eye patients comparably to placebo. Further evaluations would be needed for this mixture to demonstrate being a novel therapeutic agent for dry eye syndrome.

Recent Publications

1. Pinto Bonilla J C (2015) A randomized crossover study comparing trehalose/hyaluronate eyedrops and standard treatment: patient satisfaction in the treatment of dry eye syndrome. Ther Clin Risk Manag. 11:595-603.
2. Donnenfeld E D (2003) Experience expands the reach of restasis. Review of Ophthalmology. 10:54-6.
3. H Liang (2012) Ocular safety of cationic emulsion of cyclosporine in an in vitro corneal wound-healing model and an acute in vivo rabbit model. Mol Vis. 18:2195-2204.
4. Laibovitz R A (1993) Pilot trial of cyclosporine 1% ophthalmic ointment in the treatment of keratoconjunctivitis sicca. Cornea. 12(4):315-323.
5. Sall K (2000) Two multicenter, randomized studies of the efficacy and safety of cyclosporine ophthalmic emulsion in moderate to severe dry eye disease. CsA Phase 3 Study Group. Ophthalmology. 107(4):631-639.

Biography

Choun Ki Joo, MD, PhD has expertise in cataract, cornea, and other basic studies. He is a Dean of the College of Medicine, the Catholic University of Korea, and also President of the Catholic Institute for Visual Science.

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