

Immunosuppressive medication effectively treats ocular graft-versus-host-disease

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Reza Dana, M.D., M.Sc., MPH, at work. Credit: Mass. Eye and Ear

Researchers from Massachusetts Eye and Ear/Harvard Medical School have conducted a clinical trial comparing the safety and efficacy of topical tacrolimus, an immunosuppressive therapy, and topical methylprednisolone, a steroid medication, in patients with ocular graft-versus-host-disease (GVHD)—a complication associated with allogeneic bone marrow transplants in which the transplanted immune system's cells attack certain parts of the recipient's body, including the cornea and ocular surface. The researchers found that patients treated with tacrolimus experienced equal relief of ocular symptoms as those treated with methylprednisolone, with fewer negative serious side effects. The findings from the clinical trial, published today in *Ophthalmology*, suggest that tacrolimus is an effective therapeutic option for ocular GVHD without the known hypertensive effects of steroids.

"We found tacrolimus to be very effective—just as good as the steroid, in the reduction of ocular symptoms of GVHD," said principal investigator Reza Dana, M.D., M.Sc., MPH, Director of the Cornea and Refractive Surgery Service at Massachusetts Eye and Ear and the Claes H. Dohlman Professor of Ophthalmology at Harvard Medical School.

"We saw this improvement without any of the negative effects, such as a rise in pressure in the eye, as we saw with the steroid."

A total of 40 [patients](#) with ocular GHVD participated in the randomized, prospective clinical trial, in which 24 of those patients were treated with topical tacrolimus and 16 were treated with topical methylprednisolone twice a day for 10 weeks. The researchers observed no adverse events in either set of patients; however, intraocular pressure increased in patients treated with steroids following the completion of those 10 weeks.

A complication associated with allogeneic bone marrow transplantation, GVHD occurs when the transplanted immune system's cells attack certain parts of the recipient's body, including the corneas, which results in severe dry eye symptoms and other ocular complications.

"The problem with steroid treatment for ocular GVHD is that it can cause the pressure in the eye to rise, and it can also cause cataracts," Dr. Dana said. "The results of this trial give us reassurance that this is another effective treatment for GVHD, without the negative side effects of steroids. This is a game changer in terms of managing their care."

More information: A Clinical Trial Comparing the Safety and Efficacy of Topical Tacrolimus versus Methylprednisolone in Ocular Graft-versus-Host Disease, www.aaojournal.org/article/S0161-6420%2816%2900331-6/abstract

Provided by Massachusetts Eye and Ear Infirmary

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