# Randomized Trials On The Ocular Immunology Service

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The Ocular Immunology Service of the Massachusetts Eye and Ear Infirmary currently has active three randomized clinical trials.

1. Treatment of Macular Edema Associated with a History of Uveitis

   We are testing the hypothesis that long-term oral non-steroidal anti-inflammatory drug therapy by mouth will reduce the rate of recurrence of cystoid macular edema associated with uveitis after said edema has been successfully reversed with regional steroid injection therapy, and the uveitis has been maintained in total quiescence. The efficacy of regional steroid injection therapy is relatively well accepted, but not guaranteed. Therefore, in our protocol design, we have insisted that the patients show angiographic evidence of reversal of the macular edema within three weeks of a regional steroid injection before being randomized to a long-term oral non-steroidal anti-inflammatory drug therapy vs. placebo. The rate of recurrence of macular edema over the ensuing 12 months in the absence of recurrence of active uveitis will be the primary assessment paramenter.

2. Topical Cyclosporin Therapy for Atopic Keratoconjunctivitis

   Many patients with atopic disease become steroid dependent, and both uncontrolled and recently randomized placebo-controlled clinical trials employing topical Cyclosporin eye drops, 2%, in the care of patients with vernal keratoconjunctivitis strongly indicate that this local mode of immunomodulation can be effective for allergic eye disease. Therefore, we are engaging in a randomized, prospective, placebo-controlled, double-masked clinical trial investigating the efficacy of 2% Cyclosporin drops in a novel vehicle, with much greater patient comfort, in the care of patients with atopic keratoconjunctivitis. The primary efficacy parameter will be patient subjective assessment of ocular comfort and lack of itch, along with the investigators' assessment of presence of lack of conjunctival inflammation.

3. Posterior Chamber Lens Implantation in Patients with a History of Uveitis

We showed, many years ago, that selected patients with a history of uveitis who had developed cataract, could enjoy substantial improvement in vision through cataract surgery andposterior chamber lens implantation. However, we are also publishing on a series of patients in whom lens implantation was not successful, i.e., the lens implant eventually had to be removed because of chronic or recurrent inflammation and the formation of inflammatory "cocoon" membranes around the lens implant, with membrane contraction and progressive hypotony. We are currently engaged in an International study comparing PMMA lenses, Heparin-coated PMMA lenses, Acrylsoft lenses, and silacone lenses in the care of patients with uveitic cataract. The study is randomized, but obviously not masked. However, the International data assessment group, in Spain, is masked to the implant type during data analysis of investigators' assessment sheets of ongoing inflammation, visual acuity, membrane formation, etc.