Vision loss from retinal venous occlusive disease is estimated to be the second most common cause of retinal vascular disease (behind diabetic retinopathy) in the United States.1 Macular edema is a frequent cause of visual acuity loss in eyes with central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO).1,4 Current treatment modalities for macular edema associated with retinal vein occlusion are often unsatisfactory. The Central Vein Occlusion Study demonstrated no beneficial impact of grid laser photocoagulation on the visual acuity of patients with macular edema associated with CRVO and, at present, no treatment has been proven effective for macular edema from CRVO.4 The BVOS (Branch Vein Occlusion Study) demonstrated that grid laser photocoagulation for macular edema from BRVO may, in many cases, be an effective treatment; however, many patients derive limited benefit from laser photocoagulation.1

In the BVOS, 40% of the 43 treated eyes had worse than 20/40 vision at 3 years, and 12% of treated eyes had 20/200 or worse visual acuity at 3 years.1 Several other treatment modalities have been evaluated for macular edema secondary to retinal vein occlusion, such as laser chorioretinal anastomosis, vitrectomy surgery (with or without arteriovenous sheathotomy), radial optic neurotomy, intravitreal injection of tissue plasminogen activator, and intravitreal injection of aptamers or antibodies targeted at vascular endothelial growth factor (VEGF).5-19 Another treatment evaluated recently is intravitreal injection of triamcinolone acetonide (hereafter referred to as intravitreal triamcinolone [IVTA]) for macular edema secondary to both CRVO and BRVO. None of these treatments has yet been proven to be safe or effective. Thus, there is a need for additional treatment options for macular edema associated with CRVO and BRVO, and the identification of additional treatments that are safe and effective is of public health importance.

SCORE STUDY

The SCORE (Standard Care versus Corticosteroid for Retinal Vein Occlusion) Study, sponsored by the National Eye Institute (NEI), consists of two multicenter, randomized, phase 3 clinical trials comparing the safety and efficacy of standard care with IVTA in either a 1-mg or a 4-mg dose for vision loss associated with macular edema secondary to CRVO or BRVO. In the CRVO trial, standard care therapy is observation, and in the BRVO trial, standard care therapy is either immediate or deferred grid laser photocoagulation, depending on whether a dense macular hemorrhage is present.

STUDY OBJECTIVES

The primary objective of the SCORE study is to compare visual acuity outcomes among three groups of participants: those who are randomly assigned to receive standard care and those randomly assigned to receive one of two doses of IVTA for treatment of macular edema secondary to CRVO or BRVO. Secondary objectives include estimating the incidence of infectious endophthalmitis, noninfectious endophthalmitis,
retinal detachment, vitreous hemorrhage, cataract, and elevated intraocular pressure in eyes receiving intravitreal triamcinolone. Other secondary objectives include comparing changes in retinal thickness in participants who are randomly assigned to receive IVTA with those randomly assigned to standard care for treatment of macular edema associated with CRVO or BRVO. Study participants are followed for at least 1 year and up to 3 years after randomization.

The primary objective of the SCORE study is to compare visual acuity outcome among three groups of participants.

ENROLLMENT CRITERIA
To be eligible for the SCORE Study, patients were required to have center-involved macular edema secondary to either CRVO or BRVO. Eyes could be enrolled as early as the time diagnosis of the macular edema, but not longer than 24 months after diagnosis (by patient history or ophthalmologic diagnosis). Additional eligibility criteria include an ETDRS (Early Treatment Diabetic Retinopathy Study) visual acuity score of greater than or equal to 19 letters (approximately 20/400) and less than or equal to 73 letters (approximately 20/40) by the electronic ETDRS visual acuity protocol, and a mean retinal thickness on two optical coherence tomography measurements greater than or equal to 250 µm (central subfield). For eyes with visual acuity between 19 and 33 letters, the investigator was required to believe that the retinal vein occlusion was perfused. Additional information about patient eligibility criteria and the SCORE Study can be found online at http://spitfire.emmes.com/study/score/.

SCORE Study enrollment occurred between November 2004 and February 2008. A common close-out date of February 28, 2009 was subsequently established to allow at least 1 year of follow-up on all participants.

ANTICIPATED RESULTS
Results of the SCORE Study, anticipated to become available in the fall of 2009, will either demonstrate the efficacy and safety of an unproven treatment for macular edema associated with CRVO or BRVO or demonstrate that a commonly performed treatment is not effective or safe in the long-term.

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