

The Standard Care vs. Corticosteroid for Retinal Vein Occlusion (SCORE) Study One-Page Protocol Synopsis (Version 7.0, dated 02/10/2008)

Primary objective	<ul style="list-style-type: none"> • To compare visual acuity outcome among 3 groups of participants: those who are randomly assigned to receive standard care and those randomly assigned to receive one of two doses of intravitreal injection(s) of triamcinolone acetonide for treatment of macular edema associated with central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO).
Study design	<ul style="list-style-type: none"> • A single eye from each CRVO or BRVO participant will be randomized in a 1:1:1 ratio to one of three groups (treatment of neovascular complications as necessary in all three groups): <ol style="list-style-type: none"> 1. Standard care group: conventional treatment consisting of: <ol style="list-style-type: none"> a. CRVO: <ol style="list-style-type: none"> i. Observation of macular edema. b. BRVO: <ol style="list-style-type: none"> i. Study eyes with dense macular hemorrhage: Immediate observation. Grid laser photocoagulation will be performed if and when clearance of hemorrhage permits grid laser photocoagulation. ii. Study eyes without dense macular hemorrhage: Immediate grid laser photocoagulation. or 2. Intravitreal injection(s) of 4 mg of triamcinolone acetonide, or 3. Intravitreal injection(s) of 1 mg of triamcinolone acetonide.
Primary efficacy outcome	<ul style="list-style-type: none"> • Improvement by 15 or more letters from baseline in best-corrected ETDRS visual acuity at the 12-month visit as determined by the ETDRS visual acuity protocol.
Secondary efficacy outcomes	<ul style="list-style-type: none"> • Change between baseline and each efficacy outcome assessment visit in best-corrected ETDRS visual acuity score (e.g. mean change in visual acuity score). • Change in calculated retinal thickening as assessed by optical coherence tomography (OCT). • Change in retinal thickness at the center of the macula as assessed by stereoscopic color fundus photography. • Change in area of retinal thickening as assessed by stereoscopic color fundus photography.
Safety outcomes	<ul style="list-style-type: none"> • Injection-related events including infectious endophthalmitis, non-infectious endophthalmitis, retinal detachment, and vitreous hemorrhage. • Steroid-related toxicities including cataract and elevated intraocular pressure (IOP).
Major eligibility criteria	<ul style="list-style-type: none"> • Participants must have center-involved macular edema secondary to either CRVO or BRVO, with eyes enrolled as early as the time diagnosis of the macular edema, but not longer than 24 months after diagnosis. • Visual acuity score greater than or equal to 19 letters (20/400) and less than or equal to 73 letters (20/40) by the ETDRS visual acuity protocol in the study eye. • Retinal thickness \geq 250 microns in the central subfield of the OCT topographic map formed by six radial scans (mean of 2 measurements). • No history of laser photocoagulation for macular edema within 4 months prior to randomization.
Study procedures	<ul style="list-style-type: none"> • Electronic ETDRS protocol refraction and ETDRS visual acuity testing. • Ophthalmic examination, including IOP, lens examination, and dilated ophthalmoscopy. • ETDRS protocol 3 and 7-standard field stereoscopic fundus photography. • ETDRS protocol fluorescein angiography. • OCT
Retreatment criteria	<ul style="list-style-type: none"> • During follow-up, an assessment will be made with regard to the need for retreatment of the study eye with intravitreal injections. For those patients assigned to a standard care group, an assessment will be made with regard to the need for retreatment of the study eye with grid photocoagulation (this applies only to those patients with BRVO and without a dense macular hemorrhage). The protocol-defined retreatment criteria are based on visual acuity, clinical examination, and OCT. Eyes will be retreated unless they meet protocol-defined criteria for postponing retreatment.
Follow-up duration	<ul style="list-style-type: none"> • Participants will be followed between 12 and 36 months.
Final enrollment	<ul style="list-style-type: none"> • 682 participants: 271 CRVO participants and 411 BRVO participants.