



The Standard Care vs. Corticosteroid for Retinal Vein Occlusion (SCORE) Study

## INCLUSION/EXCLUSION CRITERIA

### General Inclusion Criteria

- a. Ability and willingness to provide informed consent.
- b. Sex: Participants may be male or female.
- c. Age: 18 years or older

### Ocular Inclusion Criteria (study eye)

- a. Participants must have center-involved macular edema secondary to either CRVO or BRVO. Eyes may 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). The following definitions are used for the purposes of the SCORE Study:
  - i. A CRVO is defined as an eye that has retinal hemorrhage or other biomicroscopic evidence of retinal vein occlusion (e.g. telangiectatic capillary bed) and a dilated venous system (or previously dilated venous system) in all 4 quadrants.
  - ii. A BRVO is defined as an eye that has retinal hemorrhage or other biomicroscopic evidence of retinal vein occlusion (e.g. telangiectatic capillary bed) and a dilated venous system (or previously dilated venous system) in 1 quadrant or less of retina drained by the affected vein.
  - iii. A hemiretinal vein occlusion (HRVO) is defined as an eye that has retinal hemorrhage or other biomicroscopic evidence of retinal vein occlusion (e.g. telangiectatic capillary bed) and a dilated venous system (or previously dilated venous system) in more than 1 quadrant but less than all 4 quadrants. Typically, a HRVO is a retinal vein occlusion that involves 2 altitudinal quadrants. *For the purposes of the SCORE Study, eyes with HRVO will be treated as eyes with BRVO and analyzed with the BRVO group.*

### General Exclusion Criteria

Participants with any of the following conditions are ineligible:

- a. A condition that, in the opinion of the investigator, would preclude participation in the study (e.g., chronic alcoholism or drug abuse, personality disorder or use of major tranquilizers indicating difficulty in long term follow-up, likelihood of survival of less than 3 years).
- b. Participation in an investigational trial within 30 days of study entry that involved treatment with any drug that has not received regulatory approval at time of study entry.
- c. History of allergy to any corticosteroid or component of the delivery vehicle.
- d. Sitting systolic blood pressure greater than 180 mmHg or diastolic blood pressure greater than 110 mmHg. If the initial reading exceeds these values, a second reading may be taken two or more hours later; the patient may be included (if all other inclusion criteria are met) in the study if the second reading demonstrates a systolic blood pressure equal to or less than 180 mmHg and the diastolic blood pressure is 110 mmHg or less. If the blood pressure is brought to 180 mmHg systolic or less and 110 mmHg diastolic or less by antihypertensive treatment, the patient can become eligible.
- e. The participant will be moving out of the area of the clinical center to an area not covered by another clinical center during the 3 years of the study.
- f. History of systemic (e.g., oral, IV, IM, epidural, bursal) corticosteroids within 4 months prior to randomization or topical, rectal or inhaled corticosteroids in current use more than 2 times per week.

- b. ETDRS 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 ETDRS visual acuity protocol.
  - c. Mean retinal thickness on two OCT measurements greater than or equal to 250 microns (central subfield).
  - d. Media clarity, pupillary dilation and participant cooperation sufficient for adequate fundus photographs.
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- g. Positive urine pregnancy test: all women of childbearing potential (those who are pre-menopausal and not surgically sterilized) may participate only if they have a negative urine pregnancy test, if they do not intend to become pregnant during the timeframe of the study and if they agree to use at least one of the following birth control methods: hormonal therapy such as oral, implantable or injectable chemical contraceptives; mechanical therapy such as spermicide in conjunction with a barrier such as a condom or diaphragm; intrauterine device (IUD); or surgical sterilization of partner.

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### Ocular Exclusion Criteria (study eye)

- a. Exam evidence of vitreoretinal interface disease (e.g. vitreomacular traction, epiretinal membrane), either on clinical examination or optical coherence tomography thought to be contributing to macular edema.
  - b. An eye that, in the investigator's opinion, would not benefit from resolution of macular edema such as eyes with foveal atrophy, dense pigmentary changes or dense subfoveal hard exudates.
  - c. Presence of an ocular condition that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., age-related macular degeneration, uveitis or other ocular inflammatory disease, neovascular glaucoma, Irvine-Gass Syndrome, prior macula-off rhegmatogenous retinal detachment).
  - d. Presence of a substantial cataract that, in the opinion of the investigator, is likely to be decreasing visual acuity by 3 lines or more (i.e. a 20/40 cataract).
  - e. History of laser photocoagulation for macular edema within 4 months prior to randomization.
    - Note: If prior grid laser photocoagulation has been performed, the study eye must have either:
      - a. One or more disc areas of leakage on the fluorescein angiogram (FA). This area of leakage must be contiguous with the fovea and have no evidence of prior laser treatment.
- OR
- b. Two or more disc areas of leakage on the fluorescein angiogram (FA). This area of leakage must be contiguous with the fovea and have evidence of clearly inadequate prior laser treatment.
- f. History of intravitreal corticosteroid injection.
  - g. History of peribulbar or retrobulbar corticosteroid use for any reason within 6 months prior to randomization.
  - h. History of panretinal scatter photocoagulation (PRP) or sector laser photocoagulation within four months prior to randomization or anticipated within the next four months following randomization.

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- i. History of pars plana vitrectomy.
  - j. History of major ocular surgery (including cataract extraction, scleral buckle, any intraocular surgery, etc.) within 6 months prior to randomization or anticipated within the next 6 months following randomization.
  - k. History of YAG capsulotomy performed within 2 months prior to randomization.
  - l. IOP greater than or equal to 25 mm Hg.
  - m. Exam evidence of pseudoexfoliation.
  - n. History of steroid-induced IOP elevation that required IOP-lowering treatment.
  - o. History of open angle glaucoma (either primary open angle glaucoma or other cause of open angle glaucoma; note: prior angle closure glaucoma is not an exclusion).
    - A history of ocular hypertension (or IOP greater than or equal to 22 mm Hg without a prior diagnosis of ocular hypertension) is not an exclusion as long as (1) IOP is less than 25 mm Hg, (2) the patient is using no more than one topical glaucoma medication, (3) the most recent visual field, performed within the last 12 months, is normal (if abnormalities are present on the visual field they must be attributable to the patient's macular disease), and (4) the optic nerve does not appear glaucomatous.
    - Note: If IOP is 22 to less than 25 mm Hg, then the above criteria for ocular hypertension eligibility must be met.
  - p. History of herpetic ocular infection.
  - q. History of ocular toxoplasmosis.
  - r. Aphakia.
  - s. Exam evidence of external ocular infection, including conjunctivitis, chalazion or significant blepharitis.
  - t. History of macular detachment.
  - u. Exam evidence of any diabetic retinopathy, defined as eyes of diabetic patients with more than one microaneurysm outside the area of the vein occlusion (inclusive of both eyes).
  - v. History of idiopathic central serous chorioretinopathy.
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**Fellow (Non-Study) Eye Criteria (the Fellow Eye Must Meet the Following)**

- a. ETDRS visual acuity score of greater than or equal to 19 letters (approximately 20/400)
- b. No prior history of intravitreal corticosteroid injection.
- c. IOP less than 25 mm Hg.
- d. No exam evidence of pseudoexfoliation.
- e. No history of steroid-induced IOP elevation that required IOP lowering treatment.
- f. No history of open-angle glaucoma (either primary open-angle glaucoma or other cause of open-angle glaucoma; note: angle-

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closure glaucoma is not an exclusion).

- A history of ocular hypertension (or IOP greater than or equal to 22 mm Hg without a prior diagnosis of ocular hypertension) is not an exclusion as long as (1) IOP is less than 25 mm Hg, (2) the patient is using no more than one topical glaucoma medication, (3) the most recent visual field, performed within the last 12 months, is normal (if abnormalities are present on the visual field they must be attributable to the patient's macular disease), and (4) the optic nerve does not appear glaucomatous.
- Note: If the IOP is 22 to less than 25 mm Hg, then the above criteria for ocular hypertension must be met